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STRENGTHENING PARTICIPATION OF SMALL BUSINESSES IN FEDERAL CONTRACTING AND INNOVATION RESEARCH PROGRAMS

HEARING

BEFORE THE

COMMITTEE ON SMALL BUSINESS AND ENTREPRENEURSHIP UNITED STATES SENATE

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

JULY 12, 2006

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ONE HUNDRED NINTH CONGRESS

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STRENGTHENING PARTICIPATION OF SMALL BUSINESSES IN FEDERAL CONTRACTING AND INNOVATION RESEARCH PROGRAMS

WEDNESDAY, JULY 12, 2006

UNITED STATES SENATE, COMMITTEE ON SMALL BUSINESS AND ENTREPRENEURSHIP, Washington, D.C.

The Committee met, pursuant to notice, at 10:38 a.m., in Room 428, Russell Senate Office Building, Hon. Olympia J. Snowe, Chair of the Committee, presiding.

Present: Senators Snowe, Bond, Coleman, Thune, Isakson, Vitter, Enzi, and Kerry.

OPENING STATEMENT OF THE HONORABLE OLYMPIA J. SNOWE, CHAIR, SENATE COMMITTEE ON SMALL BUSINESS AND ENTREPRENEURSHIP, AND A UNITED STATES SENATOR FROM MAINE

Chair Snowe. Good morning. The hearing will come to order, please. Good morning and welcome to today's hearing on strengthening the participation of small businesses and Federal contracting innovation research programs. I want to thank all of the small business representatives for being here today as we examine the small businesses' ability to succeed in the Federal procurement arena and the small business role in innovation through SBIR pro-

I particularly want to thank Inspector General Thorson for his appearance here today. It is his first appearance before this Committee since his confirmation. I want to welcome you.

According to the SBA, the small businesses received a recordbreaking amount of Federal prime contracts, \$79.6 billion in fiscal year 2005, a \$10 billion increase from the previous year. Moreover, the SBA reports that these contracts represented 25.4 percent of Federal prime contracting dollars in 2005, surpassing the overall Government statutory goal of 23 percent for the third consecutive year.

This is welcome news. The oversight I have conducted in this Committee, however, strongly suggests that caution and corrective legislation is necessary before these numbers may be accepted at face value.

It has been the President's goal that all agencies are fair in their procurement policies and unbundle those contracts that make it more difficult for small businesses to compete.

Because small businesses drive our economic growth and job creation, it is critical that these policies are upheld so small businesses have a fair and equal opportunity to do business with the Government. Small businesses propel our economy by creating jobs, strengthening communities, empowering entrepreneurs, and assuring economic revitalization in America.

With the help of Federal contracts, small firms create and retain almost half a million jobs in fiscal year 2004, and taxpayers have enjoyed a staggering \$2.5 billion in savings since 1985 through the SBA's program to break out large contracts for competition among

The Federal Government's record of meeting its promises to America's small contracts is decidedly mixed. On the positive side, some agencies have exceeded the statutory small business goal and the Government has surpassed the 5 percent goal of contracts for small, disadvantaged businesses. And the goals for aid for small, disadvantaged businesses.

At the same time, Government data has indicated that small companies owned by women, service-disabled veterans, and those located in HUB Zones, historical under-utilized business zones, have not been given fair access to Federal contracts. Regrettably, these programs have not received the support they deserved

I am particularly troubled by the SBA's decisions earlier this year to close the office of Federal contract assistants for veteran business owners. Many in Washington assume that large firms churn out all the new ideas because they have more people or more money. The truth is that small businesses are our Nation's most innovative sector.

The numbers are indisputable. America's small businesses hold 40 percent of our national patents. They obtain 13 times more patents per employee than large firms. And their patents are twice as technologically significant as large firm patents. Government agencies must be diligent about meeting the contracting goals and insuring that these contracts go to small businesses, not large corporations.

It concerns me deeply to hear recent claims that the Government has included in the small business statistics billions of dollars in awards to some of the Nation's largest corporations. Documents released by the SBA's Office of Advocacy and the Office of Inspector General has confirmed that the Government has reported billions of dollars in contracts to large corporations. This type of misleading reporting must come to an end.

Large firms posing as small must be aggressively prosecuted and debarred from Federal contracts and the Government must uphold

its obligation to small businesses.

We would be remiss if we simply accepted the status quo of the contracting environment for small businesses. Our economy flourishes when small businesses partner with the Federal Government.

Today, we will address issues surrounding the vitality of the small business innovation research program, and its companion, the small business technology transfer program. Small businesses face barriers to commercializing their new technologies through Federal contracts and subcontracts, especially at the Department of Defense.

In particular, there is a concern about the proper level of involvement for venture capital investment, and I hope that this hearing will enable all sides in this debate to achieve a reasonable compromise in this issue. And then we can resolve some of the questions at hand.

As an original cosponsor of the SBIR program legislation, which was adopted in 1982, I am proud of the program's record of directing over \$21 billion of Federal research and development funding to America's small businesses. Unfortunately, the small business share of Federal research and development dollars has historically

amounted to less than 3 percent.

Practices that exclude small firms from Federal R&D lack foresight and hinder our competitiveness. The SBA proposes for a third year to eliminate two grant programs for rural outreach and Federal and State partnership, which assists States in preparing their local small innovators for SBIR competitions. These programs leverage the infrastructure of State technology agencies and non-profit research incubators to increase the geographic diversity and competitiveness of small, high-tech firms for States such as Maine, which have comparatively low participation in Federal R&D efforts.

Clearly, this is a step in the wrong direction, especially at a time when our key competitors, such as China, are aggressively expanding their technological base by copying the very programs the SBA

is seeking to abolish.

The President's contract bundling initiative is also presently on life support. According to reports prepared by the Government Accountability Office and the SBA inspector general report last year, most agencies claim confusion about what constitutes contract bundling. And the confusion is only compounded by the fact that the SBA failed to review over 80 percent of the contracts identified as bundled.

The future economic success of our Nation requires an environment that encourages risk taking and competition. And the programs that we will discuss here today with this panel are an integral part of that effort.

With that, I will now recognize the Ranking Member of this

Committee, Senator Kerry.

OPENING STATEMENT OF THE HONORABLE JOHN F. KERRY, RANKING MEMBER, AND A UNITED STATES SENATOR FROM MASSACHUSETTS

Senator Kerry. Well, Chair Snowe, thank you very much for having this hearing and for your leadership on the SBIR and the reauthorization effort.

I hope that we will be able to do this in a bipartisan way and also in a sensible way, measuring some of the issues that are on the table and some of the information that we are anxious to get. For instance, the study that is being done, which we will talk about a little later, which I think is important to resolving some of these issues.

But, let me just start out by saying that it is important that we are having this hearing on the SBIR, and the number of the witnesses that are here is evidence of the interest in it and some of the tensions that exist, with respect to the issues. This is important

to everybody's State here, and that is why a number of Senators are here and interested in it. But I just want to say it has particularly been successful and important to Massachusetts, where we have had, literally, thousands of Massachusetts firms, including biotechnology firms that have been able to take advantage of this program and do well because of it. And it has helped the State and the country.

We are second only to California in receiving the largest number of SBIR grants. 840 grants going to Massachusetts firms in 2004, bringing in about \$300 million to small, high-tech firms. That is al-

most 14 percent of the \$2 billion in SBIR grants annually.

So, for obvious reasons, this is an important program to us. But I think it is important to the country and to the small businesses that benefit by it. And we need to keep in mind what the dynamic is between real small businesses and real start-up efforts and the purpose of the program as we go forward.

I am a little apprehensive, Chair Snowe, about reauthorizing this program, during what is left of this year, for the simple reason that SBIR's authorization doesn't expire until 2008 and we have got a \$5 million National Academy of Sciences study on SBIR that is due

out later this year.

It would be good to put that \$5 million to good use before we jump ahead, and wait until we have the results of the study. I know that Dr. Wessner is going to address that today, but we ought to think about that, at least.

Also, I am interested in the idea of working through some kind of compromise, and we can talk about that later as we go forward. There is a certain amount of controversy over the role of venture

capital in the SBIR program.

I want to assure both sides that I do approach this with an open mind, although with a certain set of principles that I think ought to guide all of us as we think about what this Committee, and what the SBA does, and about the needs of small businesses in this country.

We ought to try to do what makes the most sense for small business and for the biotechnology and venture capital community. And there may be that there is a way to find a middle ground here that

makes sense for everybody.

Obviously, important work is being done by biotechnology firms, and I have been pleased to champion, as a matter of common sense, stem cell research, R&D tax credits, and other efforts to encourage their success.

During the presidential campaign, I called for substantial increases in research for clean energy, for medicine, for advanced manufacturing, for nanotechnologies, stem cell research, and other

priorities.

I wish we were doing that today. Other countries seem to be more focused and intent than we are. I also called specifically for increases in funding for life sciences. The biological sciences, biotechnology, diagnostics, and for industrial biotechnology, such as synthetic biology, which could lead to biodegradable plastics, energy, fuels, chemicals based on agricultural waste rather than oil.

And I have long supported greater Federal support for curiositydriven, long-term high-risk research. That is what makes America different and great. So, we acknowledge here today that biotechnology has done a lot for us, and I would like to see a way for it, with Federal support, to flourish without undermining the small business aspect of the SBIR program, and we will dig into this a little bit today. We have to remember that whatever we do here to change the definition of small business with regard to SBIR is going to impact all of the SBA programs. And it would be interesting to hear what the SBA's head of size standards has to say about that issue. It would be interesting to have GAO's input.

Their recent study concludes that the program is doing well even with the recent rule clarification by SBA. Beyond the definition of small business, there are a number of other issues related to SBIR that we need to address. Last year, Senator Snowe and I were successful in having an amendment adopted, during consideration of the Defense Authorization Bill, to create a new commercial pilot program to encourage and foster the use of SBIR technology by the Defense Department.

This program has the potential of producing hundreds of millions of dollars to SBIR companies. We have 20 years of research and development, but we are still struggling to get the agencies to make

the final investment and use the SBIR products.

We also need to discuss increasing SBIR award sizes from \$100,000 and \$750,000. We need to discuss Senator Bayh's proposal to increase the 2.5 percent set-aside for SBIR projects, and how to increase the geographic diversity of the program.

And let me just say something about Federal contracting, a sub-

ject that has come up in a number of hearings recently.

The SBA is meant to be a watchdog for small businesses, with respect to Federal procurement policy, but evidently it is asleep or something is wrong. It is just not happening. Report after report speaks to loopholes in the regulations that allow large businesses to game the system, and they are, to the disadvantage of legitimate small business interests in the country.

The SBA continues to drag its feet in correcting the problem, and this has been noted bipartisanly. Despite the President's stated strategy to unbundle contracts, they remain bundled because of procurement staffing deficiencies' and small businesses are left to suffer the consequences. Meanwhile, we read press releases that tout inflated numbers for the number of small business contracts

as a supposed success story of the Administration.

Yesterday, I filed an amendment to the Homeland Security appropriations bill, which I hope will be accepted, which will actually repeal the exemption given to the Transportation Security Administration from the Federal acquisition regulations, an exemption that was granted because we deemed, after 9/11, that we needed to get going immediately. Well, I think since then we have learned that we can actually meet those goals and not harm national security while doing so.

And the fact is that when the Administration says that 25 percent of all contracts are given out to small businesses, they are not even including TSA, which is a vast number of those contracts. So, we need to get that oversight, Chair Snowe, and I hope that we are

going to do that and we can force that to happen.

And finally, the SBA has a responsibility to look out for underserved communities, and that includes veterans who are returning from Iraq, Afghanistan, and elsewhere—disabled veterans, and woman-owned and socially and economically disadvantaged businesses. That is a purpose of the agency and of this program and of this Committee.

But Federal contracting goals that have been established for these communities are never met, and they are disregarded completely by this Administration. The underserved communities are simply left wondering why these goals are established in the first place. It is just not acceptable.

So, we have got to do a better job in enforcing those goals across the Federal Government to insure that everybody has got a fair shot at these dollars. Thank you very much, Chair Snowe. I appre-

Chair Snowe. Okay. Thank you very much, Senator Kerry. I appreciated that and I am looking forward to working with you on some of these major questions that important to small businesses.

Now, I would like to recognize my predecessor on this Committee, as Chairs of this Small Business Committee, Senator Bond.

OPENING STATEMENT OF THE HONORABLE CHRISTOPHER S. BOND, A UNITED STATES SENATOR FROM MISSOURI

Senator BOND. Thank you very much, Madam Chair, and I appreciate the opportunity to be back. It is nice to be home again in these hallowed halls of Small Business.

Today I want to address particularly the biotechnology industry, and the ability or inability of it to participate in the SBIR program. Certainly we are the world leader in innovation in biotechnology due in large part to the Federal Government's 20-year partnership with the private sector to foster growth and commercialization, in the hope that one day we will uncover cures for diseases like cystic fibrosis, heart disease, cancer, multiple sclerosis, and AIDS.

However, the biotech industry was dealt a major setback in 2004, when the SBA determined that venture-backed biotechnology com-

panies could no longer participate in the SBIR program.

Prior to that decision, the SBIR program was an example of a highly successful Federal initiative to encourage economic growth and innovation in biotechnology by funding the critical start-up and development stages of a company.

Now, traditionally, to qualify for SBIR, the small business applicant had to meet two requirements, have less than 500 employees, and two, the business be 51 percent owned by one or more individuals. Now, according to the SBA, the term individual means natural persons only, whereas for the past 20 years, the term individual included venture capital companies.

As a result, biotech companies backed by venture capital funding in Missouri and throughout our Nation who were on the cutting

edge of science could no longer participate.

The biotech industry is like no other in the world because it takes many years and intense capital expenditures to bring a successful product to market. According to a study completed by the Tufts Center for the Study of Drug Development, it takes roughly

10 to 15 years and \$800 million for a company to bring just one product to market.

Now, these cutting edge companies must rely heavily on venture capital funding. It is not a luxury, it is a necessity. Consider Clorogen, a small biotech company based in St. Louis. Within the last 2 years, this early-stage company raised its first round of venture capital financing, but, due to the SBIR rules, Clorogen was forced to abandon an SBIR grant and, with it, the development of a bio-defense vaccine program that could have produced a new vaccine against anthrax.

The company has fewer than 50 employees, but it is no longer considered a small business under the SBIR rules, because it had to get venture capital funding. This story is not unique. Madam Chair, a California company, trying to target discovery of a project of a diabetes metabolic syndrome, because they got venture capital funding, was ruled ineligible and they moved to Australia and they are doing it there.

A New Jersey company delayed work on the development of an acting powder for inhalation of Cipro for use against anthrax. It could be vital, but they could not move ahead without venture capital funding.

A Wisconsin company said that, due to SBIR rules, a project for air filtering method for production of synthetic genes had to shut down. Without the funding, these things just do not go. And I would like to submit these examples, Madam Chair, for the record.

Chair Snowe. Without objection, so ordered.

Senator BOND. Prior to 2003, 40 percent of private biotech companies had major venture capital funding SBIR grants. Since then,

The SBIR program has been very successful in developing new projects with the important Federal grants, and the venture capital firms play a vital role. I am disappointed to hear that there are some who say this would just be backing large businesses. That is just not true. Venture capital firms invest in biotechnology startups for the possibility of future innovation and financial return, not to take control or run the day-to-day operations.

Dr. Zerhouni, director of the National Institutes of Health (NIH), has said that these rules undermine the NIH's ability to award SBIR funds to applicants who it believes are most likely to improve human health, which is the mission of the NIH.

And this has widespread support from patient's groups and medical health advocates, biotechnology and medical device groups who have written to Speaker Hastert and Leader Frist and, Madam Chair, I ask unanimous consent that I be able to submit that record along with my full statement and questions for several of the witnesses for the record and I will relieve you of hearing all of my views, but you can read them if you wish.

Chair SNOWE. And we most certainly will, Senator Bond.

Senator BOND. I know you will.

[Laughter.]

Chair Snowe. Without objection, so ordered.

[The prepared statement of Senator Bond and the materials referenced above follow:]

Senator Christopher S. Bond Small Business Committee Statement SBIR Biotech Grants

July 12, 2006

Madam Chair, the United States biotechnology industry is the world leader in innovation. This is due, in large part, to the Federal government's 20-year partnership with the private sector to foster growth and commercialization in the hope that one day we will uncover cures for diseases such as cystic fibrosis, heart disease, cancer, multiple sclerosis, and AIDS.

However, the biotechnology industry was dealt a major setback in 2004 when the Small Business Administration (SBA) determined that venture-backed biotechnology companies could no longer participate in the Small Business Innovation Research (SBIR) program. Prior to the SBA's decision, the SBIR program was an example of a highly successful federal initiative to encourage economic growth and innovation in the biotechnology industry by funding the critical start-up and development stages of a company.

Traditionally, to qualify for an SBIR grant a small-business applicant had to meet two requirements: one, that the company have less than 500 employees; and two, that the business be 51% owned by one or more individuals. Now, according to the SBA, the term "individuals" means natural persons only, whereas for the past 20 years the term "individual" has included venture-capital companies. As a result, biotech companies backed by venture capital funding in Missouri and throughout our nation, who are on the cutting edge of science, can no longer participate in the program.

The biotech industry is like no other in the world because it takes many years and intense capital expenditures to bring a successful product to market. According to a study completed by the Tufts Center for the Study of Drug Development, it takes roughly 10-15 years and \$800 million dollars for a company to bring just one product to market. Accordingly, the industry's entrepreneurs must seek financial assistance wherever they can find it.

These cutting-edge companies rely heavily on venture capital funding. This funding is not a luxury -- it is a necessity. Consider Chlorogen, a small biotech company based in St. Louis, MO. Within the last 2 years, this early-stage company raised its first round of venture capital financing. Yet due to the new

SBIR rules, Cholorogen was forced to abandon an SBIR grant and with it the development of a bio-defense vaccine program that could have produced a new vaccine against anthrax. The company has fewer than 50 employees but is no longer considered a "small business" under the new SBIR rules. This story is not unique. It is happening across the country.

For the past 20 years, the SBIR program has been a catalyst for developing our nation's most successful biotechnology companies. In addition to these important government grants, venture capital funding plays a vital role in the financial support of these same companies. The strength of our biotechnology industry is a direct result of government grants and venture capital working together.

Some argue that a biotech firm with a majority of venture-capital backing is a large business. This is simply not true. Venture-capital firms invest in biotech start-ups for the possibility of a future innovation and financial return and generally do not seek to take control over the management functions or day-to-day operations of the company. Venture-capital firms that seek to invest in small biotech businesses do not, simply by their investment, turn a small business into a large business. These are legitimate, small, start-up businesses. We should not punish them.

Instead, we should work together to avoid stifling innovation. Let me be clear. Our focus is to foster cures and medicines tomorrow that were once thought to be inconceivable. Industry cannot do it alone. We must nurture biotechnology and help the industry grow for the future of our economy and for our well-being.

Last year National Institutes of Health Director Elias Zerhouni sent a letter to then SBA Administrator Hector Barreto expressing concern that the new limits on eligibility for SBIR awards unduly restricts the ability of NIH to fund high quality, small companies. In the words of Dr. Zerhouni, this "undermines NIH's ability to award SBIR funds to those applicants whom we believe are most likely to improve human health, which is the mission of NIH."

Last year I introduced legislation to ensure that the biotechnology industry has access to SBIR grants, as it has had for 20 years. It levels the playing field to ensure that SBIR grants are given to small businesses based on fruitful science and nothing else. This is still a young and fragile industry, and we are on the cusp of great scientific advances. However, as Dr. Zerhouni pointed out last year, there will be profound consequences if biotechnology companies continue to be excluded from the SBIR program.

Last month Dr. Norka Ruiz Bravo, Deputy Director for Extramural Research, NIH, wrote to the GAO commenting on its recently-published report on the SBIR program. Dr. Bravo again reiterated that SBA's rules for SBIR grants were "unduly restrictive" and that "NIH believes that the impact of the current eligibility rules presents a significant roadblock in our technology development pipeline and ultimately in the speed in which important products to improve health are brought to market."

With the SBA's questionable interpretation of the SBIR regulation, we have likely put the very health of America at risk.

I was disappointed reading the testimony of one of our panelists who believes that my legislation to allow venture-backed small companies to compete on a level playing field for SBIR funds would benefit only venture capital funds. That is not my intent. Rather, the legislation will benefit small biotech and medical device companies conducting cutting-edge research and eventually the millions of American patients who eagerly await new medical breakthroughs.

That view is shared by more than 60 patient, medical health advocate, biotechnology and medical device groups who have written to Speaker Hastert and Majority Leader Frist last year urging them to pass the SABIR Act. These groups include the American Federation for Aging Research, Children's Tumor Foundation, Christopher Reeve Foundation, Cystic Fibrosis Foundation, Huntington's Disease Society of America, Juvenile Diabetes Research Foundation, Leukemia & Lymphoma Society, Muscular Dystrophy Association, National Alliance for the Mentally Ill, Nation Multiple Sclerosis Society, Parkinson's Action Network, and the Society for Women's Health Research just to name a few.

This Committee has the opportunity to include language in the SBA reauthorization that will rectify this serious deficiency. I hope we will do it. I pledge to work with you Madam Chair and other members of this Committee to see that the many deserving small business applicants that receive venture capital investment will not have to be turned away because of unduly restrictive eligibility rules. These rules run counter to and undermine the very purpose and goals of the SBIR program.

I thank the witnesses, especially Mr. Thomas Bigger, President and CEO, Paratek, who is testifying on behalf of The Biotechnology Industry Organization, for their testimony and I look forward to a fair solution to the SBIR issue.

Thank you, Madam Chair.

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Current SBIR Eligibility Rules are Limiting Cutting-Edge Medical Research

- A New York biotechnology company stated: "We have been working to take to human clinical trials a protein therapy... [That] has the ability to regenerate new nerve connections in the brain, and restore neurological function after injuries to the brain or spinal cord... [Due to the new SBIR rules] we are unable to move this potentially very important program toward the clinic."
- A Maryland biotechnology company stated: "[the company] received a Phase I and a
 Phase II SBIR from NIH to develop a novel therapeutic for cystic fibrosis. Just a few
 months into this grant we were notified by the NIH that we were no longer eligible for the
 SBIR program. The grant was terminated, the staff on this program was terminated and
 the program was cancelled."
- A California company stated: "We proposed to initiate a target discovery project for diabetes/metabolic syndrome. Company was to receive Fast Track grant of \$2M. Grant cancelled because company deemed ineligible [under the new SBIR rules].
 Subsequently, we located a modified project in Australia - funded by the Australian Government. This shifted most of the IP and work offshore."
- A North Carolina company stated: "We delayed work on influenza and drug resistant HIV programs to concentrate on later stage programs that would be more important in our current fund raising campaign."
- A New Jersey company stated: "Our project [that has been delayed until funding is found] involved the development of a long acting powder for inhalation of Cipro for use against Anthrax. The potential for military as well as Homeland Security uses were evident."
- A Wisconsin company stated: "We received \$750K for a phase II project to develop an error filtering method for the production of synthetic genes. Due to this [SBIR] rule this project most likely will be canceled and the research facility in Wisconsin will be closed with the loss of at least 3 high tech jobs."

According to a recent survey of biotechnology companies:

- 40% of private biotech companies with majority venture funding had received SBIR funds prior to 2003. Now 0% of these companies are eligible.
- 47% of private biotechnology firms have delayed or cancelled a research project due to SBIR ineligibility.
- Only 37% of private U.S. biotech companies with VC funding remain eligible for SBIR grants.

These are not just statistics: they are REAL COMPANIES, REAL JOBS, REAL LIFE-SAVING RESEARCH!

Put Patients Before Bureaucracy

November 9, 2005

The Honorable J. Dennis Hastert The Honorable Nancy Pelosi U.S. House of Representatives Washington, DC 20515 The Honorable Bill Frist The Honorable Harry Reid U.S. Senate Washington, DC 20510

Dear Speaker Hastert, Majority Leader Frist, Minority Leader Reid and Minority Leader Pelosi:

With time running out on this session of Congress, we call on you to help eliminate a regulatory interpretation stifling promising research that could improve the health and lives of people suffering from many diseases. As 60 patient groups, medical health advocates, biotechnology and medical device organizations, we urge you to pass and make law the "Save America's Biotechnology Innovative Research (SABIR) Act" (H.R. 2943 & S.1263) before Congress completes its 2005 legislative business. The bipartisan SABIR Act, authored by Congressman Sam Graves and Senator Kit Bond, is critically necessary in order to restore the eligibility for Small Business Innovation Research (SBIR) grants to majority venture capital—backed biotechnology and medical device companies that provide promise and hope for millions of American patients.

Under the SBIR program, federal research and development grants are awarded to small-business applicants. Unfortunately, recent changes in the Small Business Administration's (SBA) interpretation of eligibility standards for SBIR grants now disqualify many start-up biotech and medical device companies. Specifically, SBA regulations require that, to be eligible for a grant, a small company must be at least 51 percent owned by one or more "individuals." The SBA has recently re-interpreted "individuals" to exclude venture capital, thereby disqualifying many bioscience and device companies from receiving these important grants. For the first decades of the SBIR program, the term "individuals" was interpreted to allow venture capital backed biotech and device companies to participate in the SBIR program. Only recently has this interpretation changed.

U.S. biotech and medical device companies are working to develop drugs, vaccines, diagnostics and devices that target more than two hundred diseases, including various cancers, heart disease, Alzheimer's disease, diabetes, multiple sclerosis, AIDS, arthritis and a whole host of rare diseases. Many of these companies use the SBIR program to provide critical early-stage funding for innovative research and development (R&D). These small companies are the ones that take significant risks and develop the breakthrough research that leads to the "miracle" treatments we have come to expect from the medical technology revolution. It must be understood, however, that SBIR grants in no way sustain emerging biotech or device companies over the course of the 10 to 15 years of development required to bring a product to market. Most biotech and device companies must rely heavily on outside investors, primarily venture capital, in order to sustain their R&D efforts.

Although recent regulatory action by the SBA to clarify the issue of affiliation sought to allow participation of some companies' majority owned by other entities, it does not address the fundamental obstacle to participation of small biotech and device companies in the SBIR program. Given the critical role SBIR grants play in helping emerging biotech and device companies, it is imperative that Congress intervene.

In closing, your leadership is needed now to help innovative research move forward in order to foster breakthrough cures. On behalf of America's patients, medical technology and biotechnology, we urge you to pass the bipartisan *SABIR Act* (H.R. 2943 & S.1263) in both the U.S. House and U.S. Senate before Congress wraps up business for 2005 so the President can sign it into law.

Respectfully,

AdvaMed AIDS Vaccine Advocacy Initiative Alliance for Aging Research Alpha-1 Foundation American Autoimmune Related Diseases Association American Federation for Aging Research American Gastroenterological Association The Amytrophic Lateral Sclerosis Association Arizona BioIndustry Association Association of American Medical Colleges ВІОСОМ BioGroup of Rhode Island Tech Collective BioIdaho Biotechnology Council of New Jersey Biotechnology Industry Organization C3: Colorectal Cancer Coalition California Healthcare Institute Children's Tumor Foundation Christopher Reeve Foundation Colorado BioScience Association Crohn's & Colitis Foundation of America Cystic Fibrosis Foundation Donald Danforth Plant Science Center FasterCures Genetic Alliance Georgia Biomedical Partnership Hawaii Life Science Council Huntington's Disease Society of America Illinois Biotechnology Industry Organization Infectious Diseases Society of America Institute for the Study of Aging Iowa Biotechnology Association

Juvenile Diabetes Research Foundation Kansas City Life Science Institute Kidney Cancer Association Leukemia & Lymphoma Society Marti Nelson Cancer Foundation Massachusetts Biotechnology Council Muscular Dystrophy Association National Alliance for the Mentally Ill National Multiple Sclerosis Society National Organization for Rare Disorders New York Biotechnology Association North Carolina Biosciences Organization Palmetto Biotechnology Alliance Parkinson's Action Network Puerto Rico Industry University Research Consortium Research! America RetireSafe Society for Women's Health Research SMA Foundation St. Louis Coalition for Plant and Life Sciences Technology Council of Maryland Tennessee Biotechnology Association Texas Healthcare & Bioscience Institute Us TOO International Prostate Cancer Education and Support Network Utah Life Science Association Washington Biotechnology L Biomedical Association Wisconsin Biotechnology and Medical

Device Association

Chair SNOWE. Senator Coleman.

Senator KERRY. May I just correct Senator Bond on one thing,

quickly?

I think he said, and he may have misspoken on it, that they are not allowed to have venture capital, that firms cannot be SBIR eligible if they have venture capital backing. They are allowed, as long as it is 49 percent.

Senator BOND. When you have the problems—

Senator Kerry. It is majority owned.

Senator BOND. Yes. Majority owned, but when you are talking about \$800 million just to bring one product to market, the truly innovative, the major projects are—

Senator KERRY. Well, I understand.

Senator BOND. But 49 percent is, you know, that is a stump that is very easily jumped. It is the big investments that we have to take care of.

Chair SNOWE. Thank you. Senator Coleman.

OPENING STATEMENT OF THE HONORABLE NORM COLEMAN, A UNITED STATES SENATOR FROM MINNESOTA

Senator COLEMAN. Thank you, Madam Chair. We have a lot of witnesses. I am just going to just ask that my statement be submitted for the record, and I associate myself with the comments of my esteemed colleague from Missouri.

Minnesota has medical technology. Our folks in medical technology have experienced the same challenges that Senator Bond

has expressed regarding folks in biotechnology.

So, I will associate myself with his opening statement, and then just briefly say that I do have deep concerns about the inspector general's report and the entire state of contracting. There are some issues that we have to discuss and I hope that we get to those today, but with that, I would just ask that my statement be submitted for the record as a whole.

[The prepared statement of Senator Coleman follows:]

Thank you Madame Chair.

I commend you for holding this important hearing on federal small business contracting and on the Small Business Innovation Research program (SBIR).

In addition to pursuing essential small business pro-growth policies, such as lower marginal tax rates and increased expensing, and providing strong support for the SBA in order to keep America competitive, we can also greatly assist small businesses by ensuring their access to government R&D spending through SBIR and their share of the federal contracting market.

Although we are currently a leader in innovation and technology, I have been troubled by indicators showing that that the rest of the world is catching up to America in the areas of innovation and technology. Our ability to remain a leader in the face of intensifying global economic competition will be greatly dependent on the success not from our economic "elephants" but from the nimble

"gazelles" of small firms through their creation of highskilled jobs and high-valued added technologies.

Through SBIR, the government provides important support for small businesses to undertake pioneering but risky technological research and development work that is essential to keeping our competitive edge. This exemplary public-partnership model has been highly successful. In my state of Minnesota, SBIR has served as a critical source of R&D funding for small businesses. From fiscal years 2001-2004, 99 Minnesota small businesses received a total of \$98 million in SBIR/STTR grants and contracts from the federal government. SBIR funding has been provided to a range of companies including those in my state such as Architecture Technology Corporation headquartered in Eden Prairie with 93 employees, an engineering services and technology integration products company, which has received approximately \$60 million in SBIR funding and five-year old Blue Sky Designs – a woman-owned small business in St. Paul which specializes in recreational products for the disabled.

Without SBIR, some small businesses may not have been able to reach their potential. The SBA's decision a few years ago to prohibit small businesses that receive more than 51 percent in venture capital funding from qualifying for SBIR grants is of concern to me. This decision has had a serious impact on medical device firms, which I should note make up an important part of the Minnesota small business landscape. These firms in particular need the support of venture capital and SBIR funding to undertake their important work.

Medical technology is a win for patients, for providers, for job-creation, for global competitiveness and for policy makers who want the best medical outcome for beneficiaries. We need to help support the next generation of medical miracles and ensure our continued competitiveness in the medical devices and biotechnology fields.

As with SBIR, federal contracting is one important and direct way the government can provide support to our small businesses.

At first glance it appears that all is well with respect to small business federal contracting. Just last month (June 21), the SBA announced that small businesses received nearly \$80 billion in federal prime contracts -- a record amount – and over 25 percent of all contracting dollars for fiscal year 2005. This is the third year in a row that the small business share of federal contracts has exceeded the 23 percent statutory goal, according to the SBA. HUBZone, women-owned small business and disabled veteran-owned small business all experienced significant increases in contracting with the federal government during the last fiscal year.

That said, recent SBA Inspector General reports on federal contracting do cast long shadows on the latest contracting numbers reported by the SBA. These reports have

determined that there are significant problems with the current contracting process.

The IG's latest contract findings demonstrate that there is significant room for improvement in the federal small business contracting realm.

Problems include:

- large businesses servicing contracts intended for small businesses through regulatory loopholes or outright fraud;
- 2. improper agency crediting of large business contracts towards small business procurement goals;
- contractor classification flaws with the central contractor registry;
- 4. poor oversight by the SBA over the bundling of contracts; and
- 5. a troubling large number of decertified and proposed decertification of HUBZone firms (for FY2005 a combined total of 56 percent firms).

I am deeply troubled by the IG findings. As the lead government agency for small businesses, the SBA has the ultimate responsibility to safeguard the interests of small businesses and with respect to contracting it appears that the SBA is failing to live up to its mandated duty.

Madame Chair, it is my hope that as we reauthorize the SBA that we consider ways to address the shortcomings of federal small business contracting.

Chair SNOWE. Thank you, Senator Coleman.

Senator Enzi.

Senator ENZI. Thank you, Madam Chair. Since I am improperly seated here, I would defer to the others. I would like to make a statement, but would allow the people with more seniority on the Committee to—thank you.

Chair Snowe. Could somebody go?

OPENING STATEMENT OF THE HONORABLE MICHAEL B. ENZI, A UNITED STATES SENATOR FROM WYOMING

Senator ENZI. Madam Chair, I do want to thank you for holding this hearing. Small business innovation and research programs, and the Federal contracting programs, are vitally important for strengthening small businesses starting today's small businesses.

Your attention provides a bipartisan forum for something that we have talking about at tables from Massachusetts to Wyoming. And I thank you for allowing part of that discussion to be by Mr. Watson who is from Wyoming. He is an expert of the best kind. He is an expert by practice. His lifelong experience with successful start-up technology business in the recent years, the small business innovation research program has translated into his role as an advocate for the SBIR program to small businesses around the State of Wyoming.

As an SBIR consultant to the University of Wyoming, Gene has consistently worked to make the SBIR program accessible to the rural small businesses of Wyoming. And he has been successful. During the first 17 years of this 24-year-old program, Wyoming small businesses received a total of \$5.5 million, or 10 percent of the national per capita average.

In the last 7 years, since Gene has been working with it, Wyoming small businesses received a total of \$23 million from the SBIR program, or 110 percent of the national per capita average.

The reason for this is that Wyoming's small businesses are submitting good, competitive proposals. Unlike other programs, the SBIR program does not include formula funding, but funds the best proposals.

I appreciate Gene's success in advocacy for the small businesses that the SBIR program was meant to serve and look forward to his comments.

Though most of my comments and questions this morning will focus on innovation research programs, I want to say that the Federal contracting is vitally important to small businesses. To support our small businesses, it is in the best interest to introduce resources to our small businesses to help them grow. One of the most extensive resources is Federal purchasing of goods and services, and I appreciate Senator Snowe's comments about incorrect and improper accounting, as an accountant.

However, most small business owners do not have the time to research the Government procurement process and access this resource. I have hosted numerous procurement conferences in Wyoming to introduce small business owners to the right contacts in the Federal Government to answer their questions and help them to understand how to obtain contracts.

I look forward to working with Madam Chair and other members of the Committee to insure that small businesses have open access to Government contracts.

In Wyoming, we are working to stabilize and steadily grow our small businesses through the utilization of the SBIR program. SBIR funds the critical start-up and development stages and it encourages the commercialization of technology, product, and service. By including qualified small businesses in the R&D arena, high-tech innovation has stimulated Wyoming's small businesses, and those in other rural States.

Given the impact the program has had on Wyoming, I believe that any suggested change to this program that could alter its impact in rural States should be given serious thought. One suggested change would allow small businesses that are majority-owned by venture capital companies to participate in the SBIR program.

Given the lack of venture capital investment in Wyoming, I have concerns that making this change would harm rather than benefit Wyoming's rural small businesses. Ideally, I would like venture capitalists to consider funding more Wyoming businesses, especially considering their record of achievement.

Now, as Chairman of the Health, Education, Labor, and Pensions Committee, I also have directly heard the concerns of those industries that are unusually dependent upon venture capital for success.

Under the current SBIR program, small businesses in such industries as biotechnology may have to make the difficult choice between another round of venture capital or continued eligibility for SBIR grants. It is a complex issue. I look forward to the testimony today, and hope that the stakeholders can get together and come up with a solution.

Thank you, Madam Chair.

[The prepared statement of Senator Enzi follows:]

Opening Statement of Senator Michael B. Enzi Senate Committee on Small Business & Entrepreneurship Hearing on "Strengthening Participation of Small Businesses in Federal

"Strengthening Participation of Small Businesses in Federal Contracting and Innovation Research Programs" July 12, 2006

Madame Chair, thank you for holding this hearing. Small business innovation research programs and federal contracting programs are vitally important for strengthening today's small businesses and starting tomorrow's small businesses. Your attention today provides a bipartisan forum to hear issues that have been discussed around tables from Wyoming to Massachusetts. Thank you also Madame Chair for allowing part of that discussion to be provided by Wyoming's own Gene Watson.

Gene is an expert of the best kind, an expert by practice. His lifelong experience with successful start-up technology businesses and in recent years, the Small Business Innovation Research (SBIR) program, has translated into his role as an advocate for the SBIR program to small businesses around the state of Wyoming. As an SBIR consultant to the University of Wyoming, Gene has consistently worked to make the SBIR program accessible to the rural small businesses of Wyoming and he has been successful. During the first 17 years of this 24 year old program, Wyoming small businesses received a total of \$5.5 million or 10 percent of the national per capita average. In the last 7 years, Wyoming small businesses have received a total of \$23 million from the SBIR program, or 110 percent of the national per capita average. The reason for this is that Wyoming's small businesses are submitting good, competitive proposals. Unlike other programs, the SBIR program does not include formula funding, but funds the best proposals. I appreciate Gene's success and advocacy for the small businesses that the SBIR program was meant to serve and I look forward to his comments.

Though most of my comments and questions this morning will

focus on innovation research programs, I also want to say that federal contracting is vitally important to small businesses. To support our small businesses, it is in our best interest to introduce resources to our small businesses to help them grow. One of the most extensive resources is federal purchasing of goods and services. According to the SBA's Office of Advocacy, small businesses were awarded \$69.23 billion in federal prime contracts in 2004.

However, most small business owners do not have the time to research the government procurement process and access this resource. I have hosted numerous Procurement Conferences in Wyoming to introduce small businesses owners to the right contacts in the federal government to answer their questions and help them understand how to obtain contracts. I look forward to working with you Madame Chair and the other members of the Committee to ensure that small businesses have open access to

government contracts.

In Wyoming, we are working to stabilize and steadily grow our small businesses through the utilization of the SBIR programs. The risk and expense of conducting serious research and development (R&D) efforts are often beyond the means of many small businesses. By reserving a specific percentage of federal R&D funds for small business, SBIR protects the small business and enables it to compete on the same level as larger businesses. SBIR funds the critical startup and development stages and it encourages the commercialization of the technology, product, or service. By including qualified small businesses in the national R&D arena, high-tech innovation has stimulated Wyoming's small businesses and those in other rural states.

Given the impact that the SBIR program has had in Wyoming, I

believe that any suggested change to this successful program that could alter its impact in rural states should be given serious thought. One such suggested change would allow small businesses that are majority-owned by venture capital companies to participate in the SBIR program. Given the lack of venture capital investment in Wyoming, I have concerns that making this change would harm rather than benefit Wyoming's rural small businesses. Ideally, I would like venture capitalists to consider funding more Wyoming businesses, especially considering their record of achievement.

As Chairman of the Health, Education, Labor and Pensions

Committee, I also have directly heard the concerns of those
industries that are unusually dependent upon capital for success.

Under the current SBIR program, small businesses in such
industries as biotechnology, may have to make the difficult choice
between another round of venture financing or continued eligibility

for SBIR grants.

This is a complex issue, and I look forward to the testimony today that will address these questions in order to help the Committee develop a response. Thank you Madame Chair.

Chair SNOWE. Thank you, Senator Enzi. Senator Vitter.

OPENING STATEMENT OF THE HONORABLE DAVID VITTER, A UNITED STATES SENATOR FROM LOUISIANA

Senator VITTER. Thank you, Madam Chair. And I want to thank all of the witnesses for being here today. I look forward to their testimony, I will be brief in light of that. I also want to thank Bob Schmidt of ClevMed, who is in the audience, a leading small businessman that I have been working with on some of these SBIR and related issues.

I bring two very focused, specific interests to this discussion today. One is the SBIR program. I think it is very important and has been fairly effective in the past. But I think in the debate and discussion, we need to have a very serious discussion about possible increasing the percentage of R&D budgets reserved for small businesses, perhaps from 2.5 percent to 5 percent. I am actively working with members on that proposal. I would invite any reaction to that idea from any of our witnesses, but I am certainly widely interested in the SBIR program and that specific proposal in the context of the discussion.

I am also very, very interested in small business contracting, particularly coming out of the, in many ways, frustrating experience of hurricane recovery with Hurricanes Katrina and Rita in Louisiana. Unfortunately, in so many instances we saw that a lot of programs and a lot of rules and regulations that were set up to help integrate small business in the recovery really did not work.

I think we need to take a very hard look at revising certain programs and rules and regulations with that in mind. In so many instances, a lot of the work after the hurricanes was given to very large entities through very large, no bid, mega-contracts. And this was hurtful to the taxpayer, because billions, literally billions of dollars were wasted, and it certainly did not integrate small business adequately into the recovery process, which was very important for the recovery, in terms of getting the economy of South Louisiana and nearby States back up and running.

A good example, for instance, are the blue roof contracts that were given out to very large entities. Again, no bid, mega-contracts. And what you had happen there, as in many, many other instances, you had layer upon layer upon layer of subcontracts built up under these no bid, mega-contracts. Literally, seven, eight, nine layers.

At the end of the day, the smaller entity actually applying the blue tarp to people's roofs, first of all, was getting on the order of 3 percent of the full contract price that the prime got. Now, I know it takes something to manage a lot of entities underneath you to manage a large territory. It should not take 97 percent of the contract price. And just 3 percent going to the entity actually applying the blue roof to a home.

The other thing that is startling about that example is that the price we paid per square of blue roof was more than the price of brand new permanent roofing, good quality roofing like is on my home. Not cheap stuff, but medium grade, good quality roofing.

We paid more for a blue roof that is supposed to last 2 months than it costs to put permanent roofing on. And unfortunately, there are plenty more examples that contracts for travel trailers where we are paying an average of \$70,000 per trailer, counting the cost of hook up, and on and on.

Senator Kerry. Are they not sitting in another State?

Senator VITTER. A lot of them are—have been.

So we need to do far better in all of these regards. I have introduced a bill, the local disaster contracting fairness act, which would develop a new model, basically, a project manager model so we do not give out a huge mega-contract to a prime and allow as many layers of subs to be built up under it as they want, which inflates the cost. But we hire a project manager for a focused price, far smaller than the prime would get otherwise and then direct that project manager to hire local small businesses under it to cut down the layers of subs and get more work and more money at a cheaper cost directly to the local small businesses.

So, Madam Chair, I am very interested in talking about both of those issues, that and SBIR, and I am interested in hearing from the witnesses.

Chair SNOWE. Thank you, Senator Vitter. I appreciate those comments and you explained the experiences that have been occurring in your State, regrettably so. And hopefully we can use the reauthorization process to identify some of those issues that we can address, as well, and incorporate those changes.

Senator Isakson.

OPENING STATEMENT OF THE HONORABLE JOHNNY ISAKSON, A UNITED STATES SENATOR FROM GEORGIA

Senator Isakson. Thank you, Senator Snowe, and I appreciate very much your calling this hearing. Out of respect for this Committee and especially the distinguished panel, I am going to be very, very brief and will submit a formal statement for the record.

I associate myself with the remarks of Senator Bond of Missouri and Senator Coleman with regard to having a keen interest in the SBIR funds and any unreasonable preclusion of access to those funds to a legitimate small business, simply because of the percentage of venture capital investment in its ownership.

Having been a part of that in the past, a company that developed very small and participated in that, I think an arbitrary cutoff without some other criteria probably might penalize actual good quality research and development and ultimately, a product getting to the marketplace.

I am very interested in hearing the testimony today and appreciate the opportunity.

Thank you, Madam Chair.

Chair ŠNOWE. Thank you, Senator Isakson, and I want to wel-

come our panel here today.

First, we have Eric Thorson, who is the inspector general for the SBA and he was unanimously confirmed by the Senate just on March 31st of this year and has had over 20 years of investigative experience.

Next, we have Commissioner Joe Wynn, who is the Washington, D.C. regional director and a lifetime member of the National Association for Black Veterans.

Next is Mr. Steven Sims, who is the vice president for Programs and Field Operations Program of the National Minority Suppliers

Development Council.

Next we have Mr. Charles Wessner. Mr. Wessner will be testifying for the National Academy of Sciences. He is currently directing a series of studies centered on Government measures to encourage entrepreneurship and support the development of new technologies.

Followed by Mr. Gene Watson, a consultant to the University of Wyoming Research Office, and director to the Wyoming SBIR/STTR

Initiative.

And then we have Dr. Mike Squillante, who is currently vice

president for RMD.

And finally we have Mr. Tom Bigger, who has been serving as president/chief executive officer and director of Paratek Pharmaceuticals since 1999.

We welcome all of the panelists. We ask you to summarize your statement within 5 minutes and we will incorporate the entire statement in the record.

And we will begin with you, Mr. Thorson. Welcome.

Mr. THORSON. Thank you. Chair SNOWE. Thank you.

STATEMENT OF THE HONORABLE ERIC M. THORSON, INSPECTOR GENERAL, U.S. SMALL BUSINESS ADMINISTRATION

Mr. Thorson. Chair Snowe and distinguished members of the Committee, I appreciate very much being invited today to discuss our concerns regarding the award of Government contracts to small businesses.

I am appreciative of the assistance I have had of several of my staff behind me, particularly of our summer intern, Jessica Smith, who is making her first visit to the United States Senate, and we appreciate very much the opportunity for her to attend a hearing of this important Committee.

The Small Business Act establishes a goal of awarding small businesses to not less than 23 percent of the total value of prime contracts issued Government-wide each year. The Act further recognizes SBA's advocacy role for small businesses and directs the SBA, in essence, to take all reasonable steps to promote opportunities for small businesses.

However, as discussed in our report of SBA's top management challenges, flaws in the procurement process have allowed large companies to receive small business awards and agencies to receive small business credit for contracts performed by large businesses. My remarks today will focus on several problems affecting Government contracting opportunities for small businesses.

First, regulatory loopholes are allowing large companies to perform small business contracts. Studies have found that agencies count towards their small business goals contracts performed by companies that have either been acquired by large firms or have outgrown small business size standards after obtaining the con-

tract, but are exercising subsequent options or task orders as small businesses.

This is a serious issue for two reasons. First, legitimate small businesses lose out on important contracting opportunities. And second, policy makers are deprived of accurate information needed to assess the effectiveness of those policies.

Although the extent of such over reporting is really unknown, we believe the problem to be widespread. Another problem relates to multiple award contracts, under which agencies may obtain small business credit for using a firm classified as small, even if the firm is not designated as such for all of the procured goods or services.

This is contrary to SBA regulations, which require that a contractor meets a size standard for each product or service for which it submits an offer.

A second issue involves large companies fraudulently obtaining small business contracts or using small firms to hide the fact that a large business is actually performing the work. In the past 5 years, we have opened 69 cases involving Government contracting fraud and have obtained 24 criminal fraud convictions resulting in fines, restitutions, and settlements of over \$17 million.

However, we have yet to obtain criminal prosecution of a large business for misrepresenting its size status in order to obtain a small business contract. One reason for this is that prosecutors are reluctant to accept cases where it is difficult to show a financial loss to the Government.

Unlike where a contractor has falsified invoices, in many cases of small business contracting fraud, the Government paid for and obtained a particular good or service that it sought to procure. The fraud occurred in how the business acquired its contract, not in its execution.

Nonetheless, there is a definite programmatic and societal loss. A company that obtains a small business contract under false pretenses deprives the contracting opportunity for a legitimate small business

Another issue involves contracting officer error. Efforts to bring to prosecution cases of small business fraud have been undermined by contracting personnel at Federal agencies who do not comply or are simply unfamiliar with small business contracting requirements.

Finally, there are the problems with the accuracy of the database used to develop and report Government-wide statistics to Congress on small business awards. We have received various complaints about large businesses being reported as receiving small business awards.

Sometimes, the problem is related to a small business acquired by a large business, or a small business that subsequently grew large. But often it resulted simply from errors in entering information into the database.

So, what can be done to address these problems? To its credit, in 2003, SBA did issue a proposed regulation to require contractors performing on multiple award contracts to annually recertify their small business size.

We believe that this would provide a significant control over the accuracy and integrity of small business contracting. However,

while SBA has since issued final regulations regarding agencies obtaining recertification as to size when a contract is sold to another company, it has now been more than 3 years since the proposed rule on annual certification has been issued. This rule needs to be finalized. Alternatively, Congress could amend the Small Business Act to require annual certification.

SBA has also submitted proposed legislation recommended by the OIG to clarify that it has the authority to debar a contractor for size misrepresentation. This is important because in a recent case the agency was reluctant to proceed with the debarment, because it was uncertain whether it had the necessary authority to do so. We urge Congress to enact this proposed legislation.

Congress could establish other control processes within SBA. For instance, legislation could create an office to monitor contract integrity, including determining whether procurement agencies are complying with small business contracting requirements, and whether the agencies are accurately reporting those goals.

For our part, in order to ensure that all opportunities are pursued to help small and disadvantaged businesses obtain Government contracts, the OIG will continue to challenge SBA to improve Government-wide compliance with the goals of small business contracting, to aggressively pursue prosecutions and debarments where warranted, and to seek creative and effective ways to enhance the ability of small business to work with the United States Government.

This concludes my remarks, and I look forward to answering your questions.

[The prepared statement of Mr. Thorson follows:]

STATEMENT OF

ERIC M. THORSON INSPECTOR GENERAL U.S. SMALL BUSINESS ADMINISTRATION

BEFORE THE

COMMITTEE ON SMALL BUSINESS AND ENTREPRENEURSHIP, UNITED STATES SENATE

CONCERNING A HEARING ENTITLED:

"STRENGTHENING PARTICIPATION OF SMALL BUSINESSES IN FEDERAL CONTRACTING AND INNOVATION RESEARCH PROGRAMS"

JULY 12, 2006

<u>Introduction.</u> Chair Snowe, Ranking Member Kerry, distinguished Members of the Committee, thank you for inviting me to testify today about our activities and concerns regarding the award of government contracts to small businesses.

The Small Business Act establishes a goal of awarding small businesses not less than 23 percent of the total value of prime contracts issued government-wide each fiscal year. The Act further recognizes the Small Business Administration's (SBA) advocacy role for small businesses, and directs the SBA, in essence, to take all reasonable steps to promote opportunities for small businesses, including firms owned by minorities, women, service disabled veterans, and other disadvantaged persons, to obtain government contracts.

As you know, each year we issue a report on the major Management Challenges facing SBA. One of the challenges refers to flaws in the procurement process that have allowed large companies to receive and perform small business awards and agencies to receive small business credit for contracts performed by large businesses.

My remarks today will focus on four issues concerning small business contracting: (1) regulatory loopholes that allow agencies to count contracts as meeting their annual small business goals even if companies have been acquired, or have grown large after being awarded the contract; (2) large companies committing fraud to obtain small business contracts or using small firms to hide the fact that a large business is actually performing the work; (3) contracting personnel who may be unfamiliar with small business procurement requirements or who may not exercise proper diligence to ensure that only legitimate small businesses obtain small business contracts; and (4) inaccurate recording of contracts in the Federal Procurement Data System – Next Generation (FPDS – NG) as awarded to small businesses when, in fact, they were awarded to large businesses, and the large businesses did not make any representations that they were small businesses. I will briefly discuss each of these issues in turn.

Regulatory Loopholes. Regarding the first issue, there are several regulatory loopholes that allow large companies to perform small business contracts. Studies by the OIG, the Government Accountability Office (GAO), and SBA's Office of Advocacy have found that agencies are allowed to count towards their small business procurement goals contracts that are performed by companies that have either been acquired by large firms, or have outgrown small business size standards after obtaining the contract, but are exercising subsequent contract options or task orders.

As noted above, the OIG has identified as a Management Challenge for the SBA the need to take action to reduce regulatory loopholes that allow over-reporting of small business procurements. We believe this is a very serious issue for the Federal Government for two reasons: (1) legitimate small businesses lose out as agencies have little incentive to identify other small business contracting opportunities; and (2) policy makers are deprived of accurate information needed to assess the effectiveness of governmental policies.

Although the extent of such over-reporting is unknown, studies that we and the GAO have conducted suggest that the problem may be widespread. In fact, one review we conducted of SBA procurement (SBA Small Business Procurement Awards Are Not Always Going to Small

Businesses, Report No. 5-14) disclosed that four out of six large-dollar SBA contracts (procured from 2000 to 2002) were awarded to companies that were no longer small. SBA reported these contracts toward meeting its small business goals. Although this was allowed by regulation, the fact that SBA is reporting contracts performed by large firms towards meeting its small business goals makes it appear highly likely that other agencies, which have less interest in promoting the interests of small companies, are doing the same thing.

Another problem relates to multiple award contracts where firms may not be small for all of the goods or services covered by the contract. In other words, a contractor that only meets small business criteria for a portion of a multiple award contract is considered to be a small business for any work done under that contract. Thus, agencies may obtain small business credit for using a firm classified as small even if the firm is not designated as small for all of the procured goods or services. This is contrary to SBA regulations, which require that a contractor meet the size standard for each product or service for which it submits an offer (13 C.F.R. § 121.407). An example of this problem was recently described in a June 14, 2006, GAO briefing report entitled Commerce Information Technology Solutions Next Generation Governmental Acquisition Contract.

Large Businesses Fraudulently Obtaining Small Business Contracts. With respect to the second issue - large businesses fraudulently obtaining small business contracts - the Small Business Act provides for penalties of up to \$500,000 and 10 years in prison for such fraud in connection with an SBA small business contracting program. In the past 5 years we have opened 69 cases involving government contracting fraud and obtained 24 criminal fraud convictions, resulting in fines, restitutions, and settlements of over \$17 million. These cases have arisen under the 8(a) Business Development Program and other SBA government contracting programs, but we have yet to obtain a criminal prosecution of a large business that has misrepresented its status as a small business in order to obtain a small business contract. Reasons for the difficulty in obtaining such a conviction vary, but one problem certainly lies with the fact that, in the case of small business contracting fraud, prosecutors are reluctant to accept cases where it is difficult to show a financial loss to the U.S. Government. Unlike where a contractor has falsified invoices, in many cases of small business contracting fraud the Government paid for and obtained the particular good or service that it sought to procure. The fraud occurred in how they acquired the contract, not in its execution. Nonetheless, there is a definite programmatic and societal loss - a company that obtains a small business contract under false pretenses deprives a contracting opportunity for a legitimate small business. In a recent case jointly investigated with the General Services Administration (GSA) OIG, we obtained a \$1 million settlement from a company that made a false representation as a small business when receiving a GSA multi-year contract. We believe this settlement sends an important message to the government contracting community that false representations of size will have significant repercussions. It bears mentioning, however, that the parent company denied any liability (as is customary in civil settlements) and that the alleged misrepresentation was made by a subsidiary that had been acquired after the misrepresentations had occurred.

Contracting Officer Error. Our efforts to bring to prosecution cases of small business contracting fraud have been complicated by the third issue that I want to focus on – contracting officer error. Good cases have been undermined by contracting personnel at Federal agencies

who do not comply, or are just unfamiliar with small business contracting requirements. We have seen errors where agencies accepted bids from contractors on small business contracts, even though the contractors had not certified that they were small businesses. Other errors have included failing to request size certifications from businesses, misuse of small business set-asides to procure the products of large businesses (such as personal computers), relying on databases containing inaccurate information about small businesses, misuse of the North American Industrial Classification categories used to define small businesses, and failing to investigate discrepancies that suggest that the contractor may not meet small business criteria. Although we will continue to diligently investigate cases of contractor fraud, the reality is that juries are reluctant to return guilty verdicts in a government contracting fraud case if the Government has been negligent, or has failed to look into obvious discrepancies.

Incorrect Entries in FPDS-NG. The fourth issue concerns incorrect entries in FPDS-NG – the database used to develop and report government-wide statistics to Congress on small business awards. While we have anecdotal evidence on this issue, we do not know the extent of the problem. Over the past 3 years, we have received various complaints about large businesses being reported in FPDS-NG as receiving small business awards. In some instances, this occurred because the large business acquired a small business, or the business had been a small business and grew large. The other common reason this occurred, however, was due to input errors. As we followed up on these complaints, we found some awards where the procurement was processed using "free and open" procedures and the award recipient had not represented that it was a small business. Contracting offices have admitted that the small business designations were simply input errors. Because FPDS-NG is the database for tracking government awards to small business, it is important that the data is correct.

What can be done to correct the problems with small business contracting? To its credit, SBA has taken some steps in this area. SBA issued a proposed regulation in 2003 to require contractors performing on multiple award contracts to annually recertify their small business size. The OIG believes that an award recertification would provide a significant control over the accuracy and integrity of small business contracting. In 2004, SBA issued final regulations requiring that agencies obtain a recertification as to size when the contract is sold to another company. However, it has now been more than 3 years since SBA issued its proposed rule on annual certification. This rule needs to be finalized. Alternatively, Congress could amend section 15(g) of the Small Business Act to require annual certification. Another positive step to reduce contracting officer error would be to increase training on small business procurement for contracting personnel. While maintaining that training is the responsibility of each procuring agency, SBA stated that it has helped develop training modules and does provide training to other agencies. Even if providing small business procurement training to contracting personnel is not a direct SBA responsibility, we believe that as the advocate of small business, SBA needs to provide whatever assistance it can in this area.

SBA has also submitted proposed legislation recommended by the OIG to revise section 16(d) of the Small Business Act, clarifying that SBA has the authority to debar a contractor for size misrepresentation. In a recent case, the Agency was reluctant to proceed with debarment because it was uncertain whether it had the necessary authority under section 16(d). Therefore, this matter was referred to another agency for consideration. SBA officials suggest it is not

feasible for them to debar contractors who make size misrepresentations. While we agree that it may be administratively easier in some cases for other agencies to process such debarments, other agencies have little incentive to pursue the matter. We believe that, due to SBA's unique role as the agency primarily responsible for the set-aside programs, it should share in the responsibility for policing these programs. We urge Congress to enact the legislation we have suggested to make it clear that SBA can undertake a debarment for size misrepresentation.

Congress could also establish control processes within SBA. For instance, some SBA officials have taken the position that, since the contracting agencies verify to GSA that the information input into FPDS-NG is accurate, accuracy is an internal control issue for each procuring agency – not SBA. However, legislation could create an office within SBA to monitor contract integrity. That office could be responsible for determining whether procuring agencies are complying with small business contracting requirements and whether the agencies are accurately reporting on their negotiated small business contracting goals. Legislation could also require the head of a procuring agency to certify as to the accuracy of the reported information, and to conduct a review, through statistically valid sampling techniques or otherwise, to verify that reported information correctly reflects small business contracting activity.

Conclusion. To ensure that all opportunities are pursued to help small and disadvantaged businesses obtain government contracts, we will continue to challenge SBA to improve government-wide compliance with the goals of small business contracting; to aggressively pursue prosecutions and debarments where warranted; and to seek creative and effective ways to enhance the ability of small businesses to do business with the U.S. Government.

Thank you for the opportunity to comment. I look forward to answering any questions that you may have.

Chair Snowe. Thank you very much. Mr. Wynn.

STATEMENT OF JOE WYNN, EXECUTIVE OFFICER, TASK FORCE FOR VETERANS' ENTREPRENEURSHIP, VIETNAM VETERANS OF AMERICA

Mr. WYNN. Good morning ranking member, Chairman Snowe, and other members of the Committee.

Let me first say what an honor it is for me to have the opportunity to come before you today to share some of the collective views of thousands of veterans and service disabled veteran owners

on the topic of Federal contracting and procurement.

Though my time of service was many years ago, I still have very vivid memories of the military experience. For those that swore that oath to protect our freedoms here in America from enemies both domestic and abroad, to what do we owe them for their service? And especially those that returned with loss of limbs and other disabilities.

Though I was fortunate and not commanded to report to combat zones like Iraq and Afghanistan, I do share in the experience of many men and women who survived. I still remind myself if not

for the grace of God, go I.

Over the years, there have been many good laws passed in recognition and support of those that served, but it was not until the drafting of the Veterans' Entrepreneurship and Small Business Development Act of 1999 that Congress found that: "Veterans of the U.S. Armed Forces have been and continue to be vital to the small business enterprises of the United States; they often face great risk to preserve the American dream of freedom and prosperity; that too little has been done to assist veterans, particularly service disabled veterans, in playing a greater role in our economy; therefore, the United States must provide additional assistance and support to veterans to better equip them to form and expand small business enterprises thereby enabling them to realize the American dream that they fought to protect."

While the framers of 106–50 did a good job of laying the foundation for a program to assist veterans interested in starting or expanding the owners of small businesses, it was not until the Veterans' Benefits Act of 2003, Section 308, that a Federal Procurement Program for veterans was actually created. Under Section 308, contract officers were given the authority to restrict competi-

tion to service disabled veterans.

But even with the foundation of a great program and a new contract vehicle, it has taken an executive order from the President and follow-up letters from a member of this Committee to get agen-

cies to start implementing the laws.

As we approach the seventh anniversary of 106–50, many members of the veterans business community are still hopeful that institutions, programs or agencies created or directed to assist them will effect positive results. But while the VA Center for Veterans Enterprise has been progressing in its data collection and assistance efforts, the SBA seems to be declining in its support.

There have been seemingly very little resources directed toward assisting veterans with Federal contracting. Few contract awards

have been given to service disabled veteran-owned businesses. A strategic plan that has yet to be completed and the operation of an office to assist veteran business owners with a staff of one, which only lasted for about 1 year.

Even the SBA Office of Veterans Business Development, also created under the legislation, has reportedly received limited resources to provide assistance to educate veteran, business owners

deployed with the Guard and Reserves.

(We support Senate Bill 1014, Supporting our Patriotic Businesses Act of 2005, introduced by Chairman Snowe of this Com-

mittee.)

And in another creation of the law, the National Veterans Business Development Corporation, after more than \$12 million in appropriations over 5 or 6 years, and four leadership changes, it is still struggling to create an identity and make a difference in the lives of veteran business owners.

Agencies and large prime contractors have yet to meet their 3 percent mandatory goals for procuring goods and services from service disabled veterans. One of the biggest impediments to increasing contracts to service disabled veterans is the "Rule of Two." Contracting officers are frustrated with the difficulty of awarding procurements directly to service disable veterans. They would like greater discretion in selecting service disabled veterans to meet their agency's goals.

Some recommendations, eliminate the rule of two. Under the rule of two, service-disabled veterans suffer, the Government agency

loses the opportunity to meet its goal.

Create a level playing field for the veteran business owners. Make the order of priority for contracting among 8(a) and HUB Zone and service disabled vet programs equal, and tell contracting officers that they shall use service-disabled veterans.

Do not include service-disabled veterans in the 8(a) program. The 8(a) program was created to help compensate for more than 100 years of wrongful discrimination and exclusion of minorities from the full benefits of American society, including the Federal market-

place.

The service disabled vet program is intended to be inclusive of any American, regardless of race, who served in this country's Armed Forces, Guard, or Reserves. The service-disabled program should retain its own identity for those who have borne the battle.

Require agencies to recognize the collective past performance of service disabled vet teaming when they partner with other preference groups. This will help to expand and develop the pool of capable and qualified businesses.

Small business subcontracting plans submitted by large prime contractors should be monitored more closely. Liquidated damages or the elimination of future contracts should be enforced for those companies that fail to demonstrate a good faith effort to comply with the plan.

Also, extend the provisions of the proposed HR 3082 to allow the VA to establish a certification process for service-disabled veterans.

Let's provide a price evaluation preference of 10 percent for service disabled vets, in acquisitions conducted using full and open competition.

Direct the use of mentor/protégé programs in all Federal agencies.

Require SBA to fully utilize its Prime Contracts and Subcontracting Assistance Programs that already exist now, and increase the number of procurement marketing reps and commercial marketing reps.

And finally, increase the Government-wide small business goals from 23 percent to 28 percent. Why can't small businesses have a bigger piece of the pie? Wouldn't that really help more American? Again, thank you for the privilege to come before you and share

Again, thank you for the privilege to come before you and share these views. This concludes my statement, and I respectfully request that my written statement be submitted for the record. And I stand ready to assist you.

Chair SNOWE. Without objection, so ordered. And that will be true for all of the panelists, as well.

[The prepared statement of Mr. Wynn follows with an attachment:]

Testimony

of

Joe Wynn, Executive Officer, Task Force for Veterans Entrepreneurship President, Veterans Enterprise Training & Services Group

on

Federal Contracting and Procurement

to

The Senate Small Business Committee

Wednesday, July 12, 2006 Russell Senate Office Building Washington, D.C.

EXECUTIVE SUMMARY

Over the years, there have been many good laws passed in recognition and support of those that served in our Nations Armed Forces. Most of the major ones dealt with Health, Medical Care, Education, Rehabilitation, Homelessness, Housing, Dependents, and Burial Rights. But it wasn't until 1999, that Congress found that: (quote from the Findings Section of PL 106-50)

- "Veterans of the United States Armed Forces have been and continue to be vital to the small business enterprises of the United States;
- (2) In serving the United States, veterans often faced great risks to preserve the American dream of freedom and prosperity;
- (3) The United States has done too little to assist veterans, particularly service-disabled veterans, in playing a greater role in the economy of the United States by forming and expanding small business enterprises;
- (4) Medical advances and new medical technologies have made it possible for servicedisabled veterans to play a much more active role in the formation and expansion of small business enterprises in the United States; and
- (5) The United States must provide additional assistance and support to veterans to better equip them to form and expand small business enterprises, thereby enabling them to realize the American dream that they fought to protect."

While the framers of PL 106-50 did a good job of setting up the program in 1999 to assist all veterans interested in starting or expanding their own small businesses, it wasn't until the Veterans Benefits Act of 2003, Section 308 that a Federal Procurement Program for Veterans was created. Under Section 308, contracting officers were given the authority to restrict competition or make sole source awards for procurements to service disabled veteran owned businesses (SDVOBs).

But even with both laws on the books, it took an Executive Order from the President, #13-360 and follow up letters this year from Senator Kerry's office via the Senate Small Business Committee to get the agencies to implement the laws and do more to create procurement opportunities for SDVOBs.

Agencies and large Prime contractors have yet to reach their 3% mandatory goals for procuring goods and services from SDVOBs. The biggest impediment to increasing contracts to SDVOBs is the "Rule of Two." The Rule of Two is a major impediment to SDVOB success under PL 106-50, 108-183, and EO 13-360, and negatively effects the SDVOB community Contracting officers are frustrated with the difficulty of awarding procurements directly to SDVOBs. They would like greater discretion in selecting SDVOBs to meet their agency's goals.

INTRO:

Good Morning Ranking Member, Chairman Snowe, Senator Kerry, and other Members of the Committee:

Let me first thank you for the opportunity to come before you today to share some of the collective views of thousands of Veterans and Service Disabled Veteran Business Owners, veterans who served with honor, and many who received distinguished honors for displaying valor and courage during their period of military service for this country. Though my time of service was many years ago, as a veteran of the US Air Force with the 66th Strategic Missile Squadron, I still have a very vivid memory of the military experience.

Over the past 15 years that I have been assisting Veterans, I had never quite thought about the true difference between serving in the military versus working as a civilian until the other day while, serving in my capacity as a Commissioner of the Veterans Disability Benefits Commission, I witnessed a presentation by a Veteran who pointed out that members of the military can be called to action wherever the need arises. And that action could be a hostile action which puts you in harms way. And you can not disobey the order to proceed without serious consequence of liberty and/or life.

For those that swore an oath to protect our freedoms here in America, from enemies both domestic and abroad, to what do we owe them for their service? And especially those that returned with loss of limb(s), mentally disturbed, or other disabilities. Though I was fortunate and was not commanded to report to a combat zone, I do share in the experience of many men and women who survived it. I still remind myself, "If not for the grace of God go I."

PL 106-50, the Veterans Entrepreneurship and Small Business Development Act of 1999

Over the years, there have been many good laws passed in recognition and support of those that served. Most of the major ones dealt with Health, Medical Care, Education, Rehabilitation, Homelessness, Housing, Dependents, and Burial Rights. But it wasn't until 1999, that Congress found that: (quoted from PL 106-50, Findings Section)

- (1) Veterans of the United States Armed Forces have been and continue to be vital to the small business enterprises of the United States;
- (2) In serving the United States, veterans often faced great risks to preserve the American dream of freedom and prosperity;
- (3) The United States has done too little to assist veterans, particularly service-disabled veterans, in playing a greater role in the economy of the United States by forming and expanding small business enterprises.
- (4) Medical advances and new medical technologies have made it possible for service-disabled veterans to play a much more active role in the formation and expansion of small business enterprises in the United States; and

(5) The United States must provide additional assistance and support to veterans to better equip them to form and expand small business enterprises, thereby enabling them to realize the American dream that they fought to protect.

As a result of these findings, which by the way, were brought to light by the Task Force for Veterans Entrepreneurship, including many Veteran Service Organizations, and members of the veterans community, Congress unanimously passed the Veterans Entrepreneurship and Small Business Development Act of 1999, better known as Public Law 106-50.

As we now know, that single piece of legislation offered a remedy to the findings and created the framwork for Federal Contracting Assistance for Veteran Business Owners. The law directed that – the SBA, including the Small Business Development Centers and the Senior Core of Retired Executives, and the Departments of Labor and Veterans Affairs, do more to assist veterans with starting or expanding their own small businesses. It also called for the creation of new programs and institutions, i.e., the Center for Veterans Enterprise, the Office of Veterans Business Development, and the National Veterans Business Development Corporation.

Congress also went a step further in the legislation by calling for the creation of a Veterans Advisory Board to the SBA, and required that a goal be set for federal agencies and large prime contractors to procure a minimum of 3% of their goods and services from service disabled veteran owned businesses.

Having been a member of the Task Force for Veterans Entrepreneurship since 1999, to oversee the creation and implementation of PL 106-50, I would have to say that the members of Congress, veterans, and others who put forth the details should be commended. Its a well-rounded plan that if implemented as intended, would get veterans across the nation into the mainstream of owning a business, entrepreneurship, and thereby building capacity to employ other veterans and disabled veterans.

However, as we approach the 7th year anniversary, many members of the veterans business community are still hopeful that the ideals envisioned by the framers of PL 106-50 will become a reality. While the VA and its Center for Veterans Enterprise have been progressing in its data collection and assistance efforts, the SBA seems to be declining in its support. There has seemingly been very little resources directed toward assisting veterans as evidenced by the creation of an SBA Office for Veteran Business Owners with a staff of one, which only lasted for about 1 year.

The SBA Office of Veterans Business Development which was created under the legislation along with the position of an Associate Administrator has increased its headquarters staff size but has been given limited resources to operate four veteran business outreach centers and to provide assistance to veteran business owners with federal contracting, though efforts have been made to educate the veterans of the Guard and Reserves. Even the National Veterans Business Development Corporation, aka, TVC, with its more than \$12 million in appropriations, four leadership changes, and a few semi-veteran business resource centers, is still struggling to create an identity and make a difference in the lives of veteran business owners.

From the perspective of the federal contracting community, the OSDBUs, the Contracting Officers, and the Procurement Officials, it was just viewed as another program with a "nice idea." When veteran business owners began to pursue federal contracts they were told all to often, "PL 106-50 is just a goal. There are no teeth in it. We still don't have the mandatory authority to set contracts aside just for veterans."

So the Task Force for Veterans Entrepreneurship began to call for additional legislation to correct the apparent shortcomings referred to by federal contracting officials.

Public Law 108-183, the Veterans Benefits Act of 2003, Section 308

As a result, corrective language was drafted and inserted into the Veterans Benefits Act of 2003 under Section 308, now PL 108-183. That language called for the creation of a Veterans Procurement Program and made it "mandatory" that the Federal Government and its large Primes procure a minimum of 3% of all of its goods and services from Service Disabled Veteran Owned Businesses. Yet even more than 2 years after the passage of that legislation, agencies are still complaining about meeting the goal and there has still been very little assistance for veteran or service disabled veteran business owners seeking to enter the federal marketplace.

Executive Order 13-360

In the winter of 2004, President Bush issued an Executive Order, 13-360, via the Office of Federal Procurement Policy and the SBA, directing federal agencies to develop and implement a strategic plan to increase contracting opportunities for service disabled veteran owned businesses so that they could begin to receive the intended benefits of PL 108-183 and PL 106-50. After several months of delay, many agencies began to develop and make public their strategic plans, but they never reported on their progress at year's end. It wasn't until this year that many of the agencies did report. But many of them would point out that: "even though PL 108-183 created a mandatory requirement to contract with service disabled veteran owned businesses, it did not provide any funding to assist with the development of veteran businesses."

So what's really preventing veteran business owners from realizing the dream of owning their own small businesses? What more can the federal government do to assist them? What can this Congress do to improve what has been done already? Here's some of the recommendations and requests, that might make the difference:

Recommendations to Achieve the Goals - Legislative Fixes

1. Eliminate the "Rule of Two." The Rule of Two as introduced under PL 108-183 is contained in Part 19 FAR, and the Code of Federal Regulations (CFR) 13 CFR, Part 125. The Rule of Two states if a contracting officer knows of two or more SDVOBs that can do the work, then the requirement must be competed and a sole source award cannot be made. If sole source cannot be made, then the requirement may be competed among SDVOBs only under restricted competition.

Meeting with and talking with Federal Government contracting officers, we have found that they are often under pressure to get certain requirements awarded quickly, and although there is a SDVOB that can do the job, they routinely go to 8(a) sole source, since the Rule of Two will not allow them to deal with the SDVOB on a sole source basis. In these cases, the Government does not have time to even consider restricted competition among SDVOBs because of time factors. Thus, the SDVOB suffers and the government agency looses an opportunity to add to its 3% Goal under the law.

SBA 8(a) Firms have no such Rule and are awarded single sole source awards for their self marketing activities under part 19 FAR. For SBA 8(a) Firms there can be a multitude of 8(a) Firms and the Contracting Officer can still elect to sole source to just one without competitive procurement activity.

- 2. Create a level playing field for veteran business owners as with the 8a and Hubzone programs. The use of "May" for SDVOBs should be changed to "Shall" as with 8a and Hubzone owners. The order of priority for contracting preferences among the three groups should be equal. Our SDVOB community across the Nation wants sole source parity with 8(a) firms so our SDVOB's can reap the benefits of their hard work and self-marketing activities.
- 3. Strengthen the SDVOB program by increasing contract awards, resources, and support without including SDVOBs into the 8a program. The 8a program was created to help alleviate the more than 100 years of wrongful discrimination and exclusion of minorities from the full benefits of American society, including the federal marketplace. The SDVOB program is intended to be inclusive of any American who served in this country's armed forces, guard or reserves. The SDVOB program should retain its own identify for "those who have borne the battle."
- 4. Alleviate barriers to discrimination and provide more resources to expand and develop the pool of capable and qualified veteran and service disabled veteran business owners. And as a result more employment opportunities will be created for veterans, their families and their communities. Provide better oversight and frequent monitoring of agency strategic plans for implementing veterans' business legislation, in accordance with Executive Order 13-360. It wasn't until Senator Kerry of this Committee sent letters this year directly to agencies inquiring as to the existence of their progress reports and revised plans did any of the agencies comply with the Order.
- 5 Small Business Subcontracting Plans submitted by large companies (Primes) should be monitored more closely. Liquidated damages, elimination of future contracts should be imposed for those companies that fail to demonstrate a good faith effort.
- 6. Extend the provisions of H.R. 3082 which gives direct responsibility to the Dept. of Veterans Affairs to continue the obligation to rehabilitate those veterans that sacrificed for our Nations security and prosperity, by amending the Small Business Act to include a section entitled, "The Service Disabled Veteran Comprehensive Eligibility" amendment.

- 7. Provide a Price Evaluation Preference of 10% for SDVOBs in acquisitions conducted using full and open competition.
- 8. Allow the Department of Veterans Affairs to establish a certification process for SDVOBs. The VA and DOD are the only two government agencies authorized to grant service-connected disability status to veterans. Thus it would be quite natural for these agencies to issue a letter indicating a veterans' disability status. Absent an official certifying letter, the self-certification system that is currently in place, if SDVOB contract awardees are challenged, can be time consuming and an unnecessary burden.
- 9. Increased use of PMRs CMRs, SBA Prime Contracts Program, Subcontracting Assistance Program.
- 10. Increase the government-wide small business goals from 23% to 28%.

(For more details on suggested FAR Rule changes, refer to Attachment 1)

Thank you and this concludes my testimony.

Joe Wynn, Executive Member
Task Force for Veterans Entrepreneurship
President, Veterans Enterprise Training &
Services Group (VETS Group)
Senior Advisor, Vietnam Veterans of America
Legislative Liaison, National Association for Black Veterans
Jwynn@VVA.org
(301) 585-4000 ext 147

SUGGESTED CHANGES TO THE FAR

For reference FAR 19.5 is "Small Business"; 19.8 is "8(a)"; 19.13 is "HUBzone"; and 19.14 is "SDVOSB."

The items below are the specific words in FAR 19 that I believe have to be addresses by congress. Statutory changes have to tell the FAR Council and SBA that this is the end result we need.

Delete FAR 19.800 General, subparagraph (e). Change subparagraph (f) designation to "(e)". FAR 19.800 General, subparagraph (e) now reads:

"(e) Before deciding to set aside an acquisition in accordance with <u>subpart 19.5</u>, 19.13, or 19.14 the contracting officer should review the acquisition for offering under the 8(a) Program. If the acquisition is offered to the SBA, SBA regulations (13 CFR 126.607(b)) give first priority to HUBZone 8(a) concerns."

At FAR 19.1407 insert *(a)* at the beginning of the paragraph. Change FAR 19.1407 designation to 19.1408. At the new 19.1408 Insert paragraph (b);

"(b) The contracting officer shall insert the clause at <u>52.219-28</u>, Notice of Price Evaluation Preference for SDVO Small Business Concerns, in solicitations and contracts for acquisitions conducted using full and open competition. The clause shall not be used in acquisitions that to do not exceed the simplified acquisition threshold."

At FAR 19.1407 insert the following:

19.1407 – Price Evaluation Preference for Service-Disabled Veteran Owned Small Business Concerns.

- (a) The price evaluation preference for SDVO small business concerns shall be used in acquisitions conducted using full and open competition. The preference shall not be used—
 - (1) In acquisitions expected to be less than or equal to the simplified acquisition threshold;
 - (2) Where price is not a selection factor so that a price evaluation preference would not be considered (e.g., Architect/Engineer acquisitions);
 - (3) Where all fair and reasonable offers are accepted (e.g., the award of multiple award schedule contracts).
- (b) The contracting officer shall give offers from SDVO small business concerns a price evaluation preference by adding a factor of 10 percent to all offers, except—
 - (1) Offers from SDVO small business concerns that have not waived the evaluation preference;
 - (2) Otherwise successful offers from small business concerns;
 - (3) Otherwise successful offers of eligible products under the Trade Agreements Act when the acquisition equals or exceeds the dollar threshold in Subpart 25.4; and

- (4) Otherwise successful offers where application of the factor would be inconsistent with a Memorandum of Understanding or other international agreement with a foreign government (see agency supplement).
- (c) The factor of 10 percent shall be applied on a line item basis or to any group of items on which award may be made. Other evaluation factors, such as transportation costs or rent-free use of Government facilities, shall be added to the offer to establish the base offer before adding the factor of 10 percent.
- (d) A concern that is both a SDVO small business concern and a small disadvantaged business concern shall receive the benefit of both the SDVO small business price evaluation preference and the small disadvantaged business price evaluation adjustment (see <u>Subpart 19.11</u>). Each applicable price evaluation preference or adjustment shall be calculated independently against an offeror's base offer. These individual preference and adjustment amounts shall both be added to the base offer to arrive at the total evaluated price for that offer.
- (e) In the event that a SDVO small business concern and a HUBZone small business concern have submitted a proposal for the full and open competition subparaph (c) of this section will apply to both the SDVO small business concern and a HUBZone small business concern."

After FAR 52.219-27, Insert:

52.219-28 - Notice of Price Evaluation Preference for SDVO Small Business Concerns.

As prescribed in 19.1408(b), insert the following clause: Notice of Price Evaluation for SDVO Small Business Concerns (Jan 1999)

- (a) Definition. SDVO small business concern, as used in this clause, means a small business concern owned and controlled by service-disabled veterans.
- (b) Evaluation preference.
 - (1) Offers will be evaluated by adding a factor of 10 percent to the price of all offers, except---
 - (i) Offers from SDVO small business concerns that have not waived the evaluation preference:
 - (ii) Otherwise successful offers from small business concerns;
 - (iii) Otherwise successful offers of eligible products under the Trade Agreements Act when the dollar threshold for application of the Act is exceeded (see 25.402 of the Federal Acquisition Regulation (FAR)); and
 - (iv) Otherwise successful offers where application of the factor would be inconsistent with a Memorandum of Understanding or other international agreement with a foreign government.
 - (2) The factor of 10 percent shall be applied on a line item basis or to any group of items on which award may be made. Other evaluation factors described in the solicitation shall be applied before application of the factor.
 - (3) A concern that is both a SDVO small business concern and a small disadvantaged business concern will receive the benefit of both the SDVO small business price evaluation preference and the small disadvantaged business price evaluation adjustment (see FAR

clause 52.219-23). Each applicable price evaluation preference or adjustment shall be calculated independently against an offeror's base offer. These individual preference amounts shall be added together to arrive at the total evaluated price for that offer.

- (c) Waiver of evaluation preference. A SDVO small business concern may elect to waive the evaluation preference, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of this clause do not apply if the offeror has waived the evaluation preference.
 - Offer elects to waive the evaluation preference.
- (d) Agreement. A SDVO small business concern agrees that in the performance of the contract, in the case of a contract for
 - (1) Services (except construction), at least 50 percent of the cost of personnel for contract performance will be spent for employees of the concern or employees of other SDVO small business concerns:
 - (2) Supplies (other than procurement from a nonmanufacturer of such supplies), at least 50 percent of the cost of manufacturing, excluding the cost of materials, will be performed by the concern or other SDVO small business concerns;
 - (3) General construction, at least 15 percent of the cost of the contract performance incurred for personnel will be spent on the concern's employees or the employees of other SDVO small business concerns; or
 - (4) Construction by special trade contractors, at least 25 percent of the cost of the contract performance incurred for personnel will be spent on the concern's employees or the employees of other SDVO small business concerns.
- (e) A SDVO joint venture agrees that in the performance of the contract, the applicable percentage specified in paragraph (d) of this clause will be performed by the SDVO small business participant or participants;
- (f) A SDVO small business concern nonmanufacturer agrees to furnish in performing this contract only end items manufactured or produced by SDVO small business manufacturer concerns. This paragraph does not apply in connection with construction or service contracts.

(End of clause)

FAR Part 19.1404 Exclusions, (under the Service-Disabled Veteran-Owned Small Business Program) states:

"This subpart does not apply to-

- (a) Requirements that can be satisfied through award to--
 - (1) Federal Prison Industries, Inc. (see <u>Subpart 8.6</u>);
 - (2) Javits-Wagner-O'Day Act participating non-profit agencies for the blind or severely disabled (see <u>Subpart 8.7</u>);
- (b) Orders under indefinite delivery contracts (see <u>Subpart 16.5</u>);
- (c) Orders against Federal Supply Schedules (see Subpart 8.4);

(d) Requirements currently being performed by an 8(a) participant or requirements SBA has accepted for performance

under the authority of the 8(a) Program, unless SBA has consented to release the requirements from the 8(a) Program; or

(e) Requirements for commissary or exchange resale items."

FAR Part 19.1404 Exclusions go far beyond Public Law 108-183. Public Law 108-183 states:

"(c) Relationship to Other Contracting Preferences.--A procurement may not be made from a source on the basis of a preference provided under subsection (a) or (b) if the procurement would otherwise be made from a different source under section 4124 or 4125 of title 18,

United States Code, or the Javits-Wagner-O'Day Act (41 U.S.C. 46 et seq.)."

The FAR should not include the additional exclusions in subparagraphs (b), (c), (d) and (e) of FAR Part 19.1404, above. There is nothing in the statue (PL 108-183) that supports these exclusions.

The comments above apply to FAR articles needing changes to ensure that SDVO small business concerns are on the same level of the playing field as the HUBZone and the 8(a) small business concerns.

There is a problem that has existed more than 20 years that continues to rob business from small business. If we look at the dollars used by government agencies to purchase product and services from the General Services Administration Federal Supply Service through Federal Supply Schedules, it is shameful that these dollars ARE NOT part of the small business program. During the past fiscal year federal and state government purchased \$33,571,112,107 through 46 categories of GSA Schedules. All GSA Schedule holders are except from FAR Part 19 (small businesses) mandatory preference programs.

Under FAR Part 8.4 we find:

FAR 8.405-5 Small business.

- (a) Although the mandatory preference programs of Part 19 do not apply, orders placed against schedule contracts may be credited toward the ordering activity's small business goals. For purposes of reporting an order placed with a small business schedule contractor, an ordering agency may only take credit if the awardee meets a size standard that corresponds to the work performed. Ordering activities should rely on the small business representations made by schedule contractors at the contract level.
- (b) Ordering activities may consider socio-economic status when identifying contractor(s) for consideration or competition for award of an order or BPA. At a minimum, ordering activities should consider, if available, at least one small business, veteran-owned small business, service disabled veteran-owned small business, HÜBZone small business, women-owned small business, or small disadvantaged business schedule contractor(s). GSA Advantage! and Schedules e-Library at http://www.gsa.gov/fss contain information on the small business representations of Schedule contractors.
- (c) For orders exceeding the micro-purchase threshold, ordering activities should give preference to the items of small business concerns when two or more items at the same delivered price will satisfy the requirement.

Submitted to Senate Small Business Crnte (12 Jul 06)

Joe Wynn,
Executive Member, Task Force for Veterans Entrepreneurship
President, Veterans Enterprise Training &
Services Group (VETS Group)
Senior Advisor, Vietnam Veterans of America
Legislative Liaison, National Association for Black Veterans
Jwynn@VVA.org
(301) 585-4000 ext 147



Association for Service Disabled Veterans Association of Small Business Development Centers Interior of the United States AMVETS (American Veterans)

Veterans)
Azimuth, Inc
Black Veterans for Social
Justice, Inc.
Blinded Veterans
Association

Center for Veterans Issues Data Force Associates Enlisted Association of the National Guard ESA, Inc. HI Tech Services, Inc.

Jewish War Veterans of the USA
Korean War Veterans Association
Matelski and Associates, Inc. Military Officers Association of America
National Association for Black Veterans
National Association for Uniformed Services

National Gulf War Resource Center National Organization for Competency Assurance NY State Coalition for Fairness to Veterans Inc. Non-Commissioned Officers Association of the USA

National Coalition for Homeless Veterans

Association of the USA
Paralyzed Veterans
of America
Quality Support, Inc.
Reserve Officers Association
of the United States
Rolling Thunder
The Keefe Group
The Retired Enlisted
Association

The Veterans Advocacy
Foundation
Veterans Benefits
Clearinghouse
Veterans Business Network
Veterans Economic Action
Veterans Economic Action
Veterans Economic Action
Veterans Group
Veterans of Foreign Wars
Vietnam Veterans
of America

Vietnam Veterans of California, Inc.

Task Force for Veterans' Entrepreneurship

8605 Cameron Street, Suite 400, Silver Spring, MD 20910 Tel: 301.585.4000 Fax: 301.585.0519

MISSION STATEMENT

The Task Force for Veterans Entrepreneurship (TFVE), organized in 1998, to advocate for the development and passage of Public Law 106-50, the Veterans Entrepreneurship and Small Business Development Act of 1999, wherein Congress realized that the United States must provide additional assistance to veterans, particularly service disabled veterans, with forming and expanding their own small businesses, and thereby enabling them to "realize the American dream that they fought so hard to protect."

The Task Force, which is composed of over 200 organizations and affiliates representing thousands of veterans throughout the United States; a high percentage of which, are small businesses; has made it their mission to monitor the implementation of the programs, agencies, and organizations referenced under the law and to present a strong unified veterans' voice for virtually all of the major veterans groups, as well as, veteran entrepreneurs; and to advocate for opportunities for veterans, particularly disabled veterans, seeking assistance to succeed in small business and self-employment.

Though PL 106-50 did much to establish the infrastructure and goals for federal and prime contracting for veterans and service disabled veterans, evidence shows that the agencies did little to get contracts to veterans; and with no accountability required, government agencies, and especially their prime contractors, failed to ever meet the minimum 3% goals for service disabled veteran business owners.

Thus the TFVE continues to advocate for additional legislation, as in October 2003, when Congress and members of the administration passed legislation that was signed into law by the President. Under that Public Law, 108-183, a Veterans Procurement Program for Service Disabled Veteran Business Owners was created. Contracting officers were authorized more "tools to work with" to achieve the mandatory minimum 3% requirements of the law. Now procurement officials can restrict or sole source contracts exclusively for Service Disabled Veteran Owned Businesses (SDVOBs). Though the veterans' community has had a great deal of optimism surrounding this piece of legislation, there is still a lack of urgency within many of the agencies to implement the program.

Therefore, the TFVE will continue its vigilant oversight of legislation and continue its advocacy of ideas in the areas of acquisition, planning, marketing, and outreach to ensure that veterans and service disabled veterans receive the full benefits of this program as promised to them by Congress, and that the language of the law is implemented "expeditiously and transparently," now as opposed to later! For additional info about the Task Force and the Veterans Procurement Program and other initiatives Goto: www.VVA.org or www.ASDV.org

Note: The TFVE meets monthly throughout the Nations Capitol to discuss the issues pertinent to the success of Veteran Business Owners. For more information contact Joe Wynn at JWYNN@YVA.org

Chair Snowe. Mr. Sims.

STATEMENT OF STEVEN SIMS, VICE PRESIDENT, FIELD OPERATIONS PROGRAM, NATIONAL MINORITY SUPPLIER DEVELOPMENT COUNCIL

Mr. SIMS. Good morning, Chairman Snowe, ranking member Kerry, and other members of Senate Small Business and Entrepreneurship Committee.

Realizing how tough it is to stay within this 5-minute timeframe,

I am going to try to be as brief as possible.

For those of you that are not aware, the National Minority Supplier Development Council is a 34-year-old organization established by corporation America to provide access and opportunity for racial and ethnic minority groups to do business with corporations.

We have most of the Fortune 1000 as members of our organiza-

tion.

Steve Rineman, chairman and CEO of PepsiCo, is the chairman of our board.

John Patterson, vice president of worldwide sourcing for IBM, is our vice chair.

And we provide services to our corporate members and to our 16,000 certified minority businesses through a network of 39 local operations councils around the country and in Puerto Rico.

We are finding an increase in the number of corporations joining NMSTC, even in light of the mergers and acquisitions because of what they perceive is the value that we bring to the table.

I would like to spend a brief time talking about five observations regarding the Small Business Association. I was at the hearing last week when you talked to the SBA administrator nominee. I do hope that, as he mentioned, his tenure will be a change, and a change for the positive for small minority businesses.

First issue, contract bundling continues to be a serious challenge to the survival and growth of minority businesses. Not one Federal contract has been unbundled in the 18 to 24 months since the President proclaimed support unbundling Federal contracts. And a GAO report came out saying that there has been no evidence of cost savings resulting from contract bundling.

Procurement opportunities, as reported by Federal agencies point to less, not more, utilization of small minority businesses. I agree with Senator Kerry that the goals have not been reached over the last 5 years. The bulk of procurement opportunities are going to smaller and smaller contractors. A number of the contractors that tend to be larger and larger companies.

A personal issue I have is certification of minority businesses. For years, we have accused SBA of their program of 25 percent of their businesses being front companies. And because it is not monitored or managed, they have not been able to refute that.

The failure of monitoring their database and utilization of self-certification process provides front companies ample entree into

this program.

And the chaos and turf wars that exist among the folks at SBA is also a barrier that restricts and retards the efforts of the agency to serve minority small businesses.

Minority businesses are the fasted growing minority, and women-owned businesses, are the fasted growing area of small business, which purports to be the engine driving America. And I do not understand, if that is the case, how we can provide a census of these critical businesses only once every 5 years, and then delay another 2 years while the information is being compiled and analyzed before it is released to the public. There is no private corporation in America that would wait 7 years to ask its customers how it is doing and what it needs to change.

Focusing on recommendations, Federal agencies need to be unbundled. But not only focus on unbundling, but then focusing on

increasing capacity.

Secondly, SBA needs more tools and procedures which makes identification and contracting with small minority businesses easier and not more difficult. SBA needs a reliable, proved certifying body for minority businesses. What it has does not work. I have offered to debate whoever is in charge of certification at SBA. It has not worked. It will not work the way it is set up.

SBA needs leadership with strong business acumen and, looking at Mr. Preston's background, hopefully he will bring that business acumen and leadership to the fore. The economic realities require at least a biannual, at minimum, survey of minority and womenowned businesses so that we can see what their issues are, what their challenges are, and what their successes are.

Two items not referenced earlier that I would like to talk about is encourage SBA to continue its effort to establish a disaster response plan which is grounded in reality and utilizes organizations and procedures that promote small minority business participation with a focus on local content making local businesses and individuals involved in the process.

And the other thing is, given the amount of money that is going down for the rebuilding effort, it seems to me the nature of the disaster requires something being done outside the usual methods. And the notion of greater transparency to make sure that the money given by the Federal Government to the States and the counties, et cetera, are actually going where it is supposed to go. And all individuals and communities are participating.

Since the tragedy did not exclude anyone based on race or ethnic characteristics, then the clean up and rebuilding should not either.

Finally, we wrestled on the minority business side with this issue of venture capital participation, and maybe in the question and answering, I could talk a little bit about how we addressed that and to continue to allow minority businesses to play in the game.

Thank you.

[The prepared statement of Mr. Sims follows:]

National Minority Supplier Development Council

1040 Avenue of the Americas, 2nd Floor, New York New York 10018, (212) 944-2430 1220 19th Street N.W., 2nd Floor, Washington DC 20036, (202) 955-0036, ssims@nmsdcus.org

Testimony
of
Steven Sims
Vice President
National Minority Supplier Development Council
before
U.S. Senate Small Business and Entrepreneurship Committee
July 12, 2006

Good Morning Chair Snowe, Ranking Member Kerry and other members of the Senate Small Business and Entrepreneurship Committee. It is an honor to be here before one of the truly bipartisan committees operating on Capital Hill. I hope my brief presentation this morning will reinforce successful current practices and support for new initiatives which will utilize the talents of all American individuals and companies as we operate more and more as part of a global economy.

What is NMSDC?

The National Minority Supplier Development Council (NMSDC) is a 34 year old organization created by Corporate America, with the assistance and support of the then U.S. Department of Commerce's Office of Minority Business Enterprises in 1972. NMSDC was created for the specific purpose of providing access and opportunities for corporations and minority-owned businesses to contact and contract with each other. We currently serve more than 3,600, corporations including many of the Fortune 1,000. Our database has more than 16,000 certified minority-owned businesses and they are served through a network of 39 affiliated councils around the United States and in Puerto Rico. In 2004, our corporations reported more than \$89 billion in contracting with minority suppliers. We are considered the pre eminent minority business organization in the United States.

NMSDC provides a wide array of services to its corporate members and certified minority businesses. These services include certifying of minority businesses, access to contracting opportunities, working capital loans, training and mentoring assistance, technical assistance, business opportunity fairs, local and national recognition and awards, research and data sharing, etc. With the changing demographics in America, more corporations are realizing the value of doing business with minority suppliers. They join NMSDC in greater numbers with each passing year to source certified minority—owned firms. Over the last ten years, NMSDC has begun exporting its model of inclusion to countries wrestling with how to include all its citizens in securing or expanding market share in a more competitive and global economy. We now boast sister organizations in Brazil, Canada and the United Kingdom. Additionally, NMSDC is currently responding to request for assistance from business communities in South Africa, Australia and China.

NMSDC OBSERVATIONS

NMSDC has operated a government relations office, in Washington DC since 1990. As director of this office, I have interacted with and sought to work with every SBA Administrator since that time to improve contracting opportunities for small and minority businesses. I was able to attend the confirmation hearing recently of the newest SBA Administrator nominee, Steven Preston. Like you, I hope his tenure will be a change from the confusion, obfuscation and disinterest of the current leadership to the plight of small and minority businesses. To be direct and to the point, the following are the observations of NMSDC:

- 1. <u>Contract bundling</u> continues to be a serious challenge to the survival and growth of minority businesses. NOT ONE FEDERAL CONTRACT HAS BEEN UNBUNDLED in the 18 months since the President proclaimed his support for unbundling federal contracts. In a roundtable meeting just three weeks ago up here on the hill, I learned of a GAO study which noted no evidence of cost savings resulting from contract bundling.
- 2. <u>Procurement opportunities</u>, as reported by federal agencies, point to less not more utilization of small and minority owned businesses. Procurement

goals have not been reached over the last five years. The bulk of procurement opportunities are going to a smaller and smaller number of contractors who tend to be larger and larger companies.

- 3. <u>Certification of minority businesses</u> for participation has been a real SBA failure by the intended goals of this initiative. For years, NMSDC has stated that the SBA small disadvantage business (SDB) database had about 25% of its listing made up of front companies or ineligible companies. SBA acknowledged it could not refute the accusation because it could not and would not set up a process to monitor businesses in this database. The failure of monitoring their database and utilization of a self certification process provided front companies ample entry into its program.
- 4. Chaos and Turf Wars have occupied the attention of many folks at the SBA national office. NMSDC has enjoyed a strong and productive working relationship with many of the SBA Regional Office and Business Development Centers. I have been impressed with the dedication and cooperation exhibited by our public sector counterparts out in the field. I wish I could say the same for the national headquarters. I believe there are best practices in both the pubic and private sectors which can and should be shared. Through this sharing, we increase the chances and opportunity to grow and develop the next generation of outstanding entrepreneurs. This has not and will not be possible until the focus of the agency leadership is on small business and not internal battles for power and influence.
- 5. Minority Business is one of the fastest growth areas of small business in the United States. Small business is touted as the engine moving America forward. Small business not only provides jobs but just as important, promote "the American Dream" of owning a piece of prosperity and success which is a clear motivation for many of our aspiring entrepreneurs. If that is the case, how can we provide a census, of these critical businesses, only once every five years, which is then delayed another two year delay before the compiled and analyzed data is released to the public? How can you as legislators respond to marketplace challenges, provide legislative and/or regulatory assistance and ensure equal access and opportunity when the information is outdated by the time it arrives in your hands.

While there are other concerns/issues we could share with you, I want to focus on potential solutions to the concerns thus far outlined.

NMSDC Recommendations

NMSDC is willing to work with those public and/or private sector entities committed to small minority business development and utilization. Let me start by saying, I have been assured that some of the following recommendations are included in the SBA Re-authorization legislation current under consideration. The NMSDC believes:

- 1. Federal Agencies need to unbundle contracts. The government needs to unbundle as many federal contracts as possible as quickly as possible. Since no financial benefits or savings have proven to accrue to the government, as a result of bundling, then let's spread the wealth and provide more opportunities to more entrepreneurs. Even as we propose this, it is critical to focus on the other side of the coin and develop strategies and programs which increase the capacity of successful small minority businesses. There is a real need to explore incentives which promote small business growth with a focus on increasing capacity so they can compete with bigger businesses.
- 2. SBA needs more tools and procedures which make identification and contracting with small minority businesses easier. The problems here are significant and ongoing. There should be tools and procedures which make identification and contracting with small minority businesses easier. Contracting officers must be assisted and encouraged to source databases. as simple and user friendly as possible, for legitimate and certified minority businesses. There needs to be enforcement of laws on the books against companies that list minority suppliers on their team but never contact these vendors after the contract is awarded. The government should seek liquidated damages from these violators, which are a remedy available under the law, and thus set an example that will have more companies obeying the law. Monitor and sanction those no longer eligible for participation in the 8 a program so that large businesses which might have started in the program and outgrown its ability to assist or those who have gotten in by other means are removed as quickly and as efficiently as possible.

- 3. SBA needs a reliable proven certifying body for minority businesses. NMSDC strongly believes the federal government should avail itself of proven leaders in the field of certification for advice and enthusiastic acceptance of their certification policies. NMSDC and WBENC, Women's Business Enterprise National Council, currently are the certifiers of record for corporate America, for minority and women suppliers respectively. It would benefit corporations and minority businesses if there was a process that promoted/supported one place to go for minority or women suppliers for either the public or private sector needs. Many corporations support this idea and would be willing to go on record in supporting public sector acceptance of these private sector certifiers. The states of Colorado, Indiana, Texas and Michigan are just a few that accept NMSDC certification or allow us to do their certification of minority vendors wanting to do business with their state.
- 4. SBA needs leadership with a strong business acumen who can straighten out its house. Interagency focus on small minority business is not going to happen until some order is brought to the agency. The best Administrator we have seen at SBA was a former business person, Mr. Erskine Bowles, who in the short time at its helm, used his business experience and acumen to provide focus and order enough to get some critical things done. Mr. Preston's background may lend itself to providing the same kind of productive movement forward.
- 5. The economic realities require a bi-annual minority and women's business census. The U.S. Department of Commerce should collects census information on Minority and Women Businesses bi-annually. Results should be compiled, analyzed and disseminated within 18 to 24 months of the census completion. This would better support and assist in formation of programs and policies critical to small minority businesses. This should be viewed as an integral part of keeping our national economic engine running.

Two items not referenced but still important are:

Encourage SBA to continue its efforts to establish a disaster response plan which is grounded in reality and utilizes organizations and procedures that promote small minority business participate and utilization. A focus on local content, making sure local businesses and individuals are contracted with and employed, with a priority on capacity, either directly or through joint ventures that allows them to go after meaningful work and not just as 10th tier contractors. The next disaster is just a matter of time and whether natural or man made will need a better level or governmental reaction and assistance than we saw last year.

Lastly, the magnitude of last year's disaster, in my opinion, requires special oversight on funds allocated to respond to this extraordinary occurrence. While this may be an action undertaken by a different committee like Government Oversight, Housing and Urban Development or Homeland Security, the impact on small business should require maximum transparency and monitoring of dollars provided to the Gulf States for clean up, rebuilding and development. Otherwise the opportunity for cronyism, corruption and malfeasance are multiplied. I would think it particularly important that all businesses and individuals of those states, cities and counties are included regardless of race, ethnicity, gender, etc. Since the tragedy did not exclude anyone based on their racial or ethnic characteristics then the clean up and rebuilding should not either.

Madam Chair, Ranking Member and committee members let me thank you for this opportunity to share NMSDC's concerns and recommendations with you and I would be happy to respond to any questions you might have at the appropriate time.

Chair Snowe. Thank you, Mr. Sims. Dr. Wessner.

STATEMENT OF DR. CHARLES W. WESSNER, DIRECTOR FOR TECHNOLOGY, INNOVATION, AND ENTREPRENEURSHIP, NA-TIONAL RESEARCH COUNCIL, NATIONAL ACADEMIES OF SCIENCE

Dr. WESSNER. Thank you, Madam Chairman. It is a pleasure to have the opportunity to address your committee today, and I would like on behalf of the National Academies to take a somewhat more conceptual approach to the SBIR program. One of the things I would like to talk about is how the SBIR program works and try to impart a better understanding of early stage finance in the United States. I want to talk a little bit about the Valley of Death, the role of SBIR in crossing that valley, and the expectations we should have for such a program.

As all of you I am sure believe, markets are very good and very powerful institutions. They are certainly better than the alternative. That said, they are not perfect, and one of the things that is very important to keep in mind is that investors have less than

perfect information.

What I want to address is why do we have this program, and I think that can be very instructive for some of the issues that will be raised in the rest of the discussion.

We have what our economist friends call "asymmetric information." I asked one of my colleagues, a leading economist by the name of David Audretsch, what he meant by asymmetric information, and he said, "Well, it means, Chuck, that it is often hard for small companies to get money." And that is, in fact, why we have the program.

A point to keep in mind is that the development of new technologies within our national economy is not automatic. The rest of the world has understood that point. They are taking measures to attract and develop new industries while in this country we are rooted in myths about how the United States has developed only through market actions. The rest of the world is taking an infinitely more practical results-oriented approach, what I would actually call a "practical Yankee approach" of the sort that helped develop our country.

Next, please.

This Valley of Death is what the new entrepreneur encounters. Now, forgive me for this simple approach, but sometimes pictures represent a thousand words, and I do not have the time for the thousand words, nor do you have the patience. But the key thing is we are putting about \$132 billion in Federally funded research each year. We are spending only about \$2 billion, unless you want to add in the \$140 million Advanced Technology Program, to get the results of the research across this valley and into the market.

Now, you may think, well, don't we have venture capital? Won't the venture capitalists take care of that? Well, if you ask some policy people here in Washington, they will say it will. But if you ask the venture capitalists, you get a rather different answer. Now,

why is that? Next, please.

Well, the point is that although our venture capital markets are the best in the world, they are broad and deep, they nonetheless have limitations. Venture capitalists actually have very limited information on new firms. They are also prone to fashion. There are herding tendencies, as any of you who have witnessed the dot-com boom would remember. Things that are really good ideas, like Google, are not always obvious at the concept stage. Keep in mind, Google tried a number of venture capital firms, firms that refused to fund them (to their infinite regret), before they finally found one that would invest in them. My point is simply that these investment decisions are not so obvious either in the private or the public sector.

So the point is that the venture capital market often lacks information on potential information and is not focused on early-stage firms. Next, please. And if you look at this breakout, less than 3 percent of the \$20-plus billion goes to early-stage investments—and there are only about 3,000 deals overall. So, in fact, the SBIR program plays a really critical role in providing initial start-up funding. I think some of the gentlemen next to me who have actually started firms would affirm that it is your first million that is the hardest money to get. It is that first financing you need, to prove the viability of your ideas and that is the role that SBIR plays.

Now, one of the other things I would like to talk about—next chart, please—today is what role the SBIR concept plays in the U.S. innovation system as a source of finance for new ideas and new companies. What we need to avoid is the old slogan that "It is not the Government's role to be picking winners and losers." With all respect, that is one of the most mindless expressions that we have on these topics. The irony is that the Government actually is quite good at picking winners. The losers will take care of themselves. Early-stage technology awards are a lot like shooting baskets.

The point of SBIR is that the Government has needs, and then the companies come up with ideas to meet those needs, whether it is an idea to solve the problem of potential bioterrorism, whether it is an idea like the Silver Fox that we have in use in Iraq today. A Silver Fox is a very inexpensive—running at \$40,000 to \$60,000 for a drone that is effectively supporting our troops.

The set-aside funding—and I commend you, Senator Snowe. As a Congressman, you supported the idea of using a set-aside so that we have a reliable stream of funding for this program. It is one of the attributes of SBIR that has attracted attention around the world.

I should just point out in a parentheses that while we debate whether we should be doing these things, Senators, the rest of the world is copying the program, often with larger awards. It is important to keep that in mind, that we do not live in a world where we determine the frame of competition. The rest of the world is determining what that competition will be.

One of the things that is really important about this ingenious program is it has tremendous flexibility. It does not use a one-size-fits-all approach. Each agency's management gets to administer the

program in the way they think best meets their needs.

Next, please.

Now, when we talk about what the program should be accomplishing, I am tempted to ask, Compared to what? What exactly should we be expecting from this program? If you look at biopharma, these are the big guys, lots of smart people, large numbers of people, billions of dollars put into new drug development, and you are all familiar, I trust with the dreadful X, the one that shows the cost of drug development going up dramatically and the one that shows results going down dramatically. So pharma has trouble getting new ideas developed and into the market. Because of this, you will hear, I think, later on, the importance that pharma attaches to these new SBIR-funded companies.

How about private venture capitalists? I enjoy the joke, Madam Chairman, that, you know, the Government cannot pick the right company for awards, but the venture capital industry can. They bring the best and the brightest together; and they succeed 2 out of 20 times while those poor dumb Federal bureaucrats can only succeed 1 out of 10. So you see the difference.

[Laughter.]

Dr. Wessner. The point is that what we have to keep in mind here is what are the realities of early-stage finance. We have to recognize that there is a high skew in outcomes, that there will be few genuine mega successes, but those mega successes are absolutely important. During questions, if you wish, I can describe what some of those successes are.

In addition to a few major successes, there will be a lot of just good work done with the SBIR awards. There will also be projects that do not succeed. But, you know, we learn from failure. Knowing that this is not a successful line of inquiry tells the Government you do not want to put hundreds of millions of dollars on this idea.

Dr. Irwin Feller, a distinguished economist who is on our team of some 20 researchers looking at this program, describes the program as "a low-cost, technological probe." It actually does lots of other things, but that is one very apt description.

So I think what we need to do is to bring realistic expectations to what constitutes success for the SBIR Program. At the same time, we should recognize that the rest of the world thinks that this is one of the best U.S. programs. Countries as diverse as Sweden, Taiwan, Korea, the Netherlands, Finland, and the United Kingdom have all emulated this program, sometimes quite directly, and they are doing many other things to support high-tech companies. I appreciate the opportunity to appear before you, Senator, and I look forward to discussing our report with you in the future.

Thank you, Madam Chairman.

[The prepared statement of Dr. Wessner follows:]

Testimony of Charles W. Wessner National Research Council

To the United States Senate Small Business and Entrepreneurship Committee

July 12, 2006

The Small Business Innovation Research Program



Good morning Senator Snowe and members of the Committee. My name is Charles Wessner, and I work at the National Research Council's Board on Science, Technology, and Economic Policy. The National Research Council is the operating arm of The National Academies, which consists of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. Currently, the National Research Council is conducting a major assessment of the Small Business Innovation Research (SBIR) program at the request of Congress. My remarks today do not focus on findings and recommendations of that study, which is now in its final stages, but will instead draw on a conference report that addresses the role of SBIR as a source of early-stage finance in the U.S. innovation system.

SBIR'S ROLE AND STRUCTURE

Created in 1982 through the Small Business Innovation Development Act, SBIR offers competition-based awards to stimulate technological innovation among small private-sector businesses while providing government agencies new technical and scientific solutions to help agencies achieve mission objectives. SBIR also encourages small businesses to commercialize innovative technologies in the private sector, helping to stimulate U.S. economic growth and international competitiveness.

As conceived in the 1982 Act, SBIR's grant-making process is structured in three phases:

- Phase I is essentially a feasibility study in which award winners undertake a limited amount of research aimed at establishing an idea's scientific and commercial promise. Today, the legislation anticipates Phase I grants as high as \$100,000.2
- Phase II grants are larger normally \$750,000 and fund more extensive R&D to further develop the scientific and technical merit and the feasibility of research ideas.

¹ This testimony is drawn from the National Research Council Report, The Small Business Innovation Research Program: Program Diversity and Assessment Challenges, Report of a Symposium, Washington, D.C.: National Academies Press, 2004

² With the accord of the Small Business Administration, which plays an oversight role for the program, this amount can be higher in certain circumstances; e.g., drug development at NIH, and is often lower with smaller SBIR programs, e.g., EPA or the Department of Agriculture.

Phase III. This phase normally does not involve SBIR funds, but is the stage at which grant recipients should be obtaining additional funds either from a procurement program at the agency that made the award, from private investors, or from the capital markets. The objective of this phase is to move the technology to the prototype stage and into the marketplace.

Phase III of the program is often fraught with difficulty for new firms. In practice, agencies have developed different approaches to facilitating this transition to commercial viability; not least among them is the use of additional SBIR awards.³ Some firms with more experience with the program have become skilled in obtaining additional awards.

Previous NRC research showed that different firms have quite different objectives in applying to the program. Some seek to demonstrate the potential of promising research. Others seek to fulfill agency research requirements on a cost-effective basis. Still others seek a certification of quality (and the investments that can come from such recognition) as they push science-based products towards commercialization.⁴

Features that make SBIR grants attractive from the firm's perspective include the fact that there is no dilution of ownership or repayment required. Importantly, grant recipients retain rights to intellectual property developed using the SBIR award, with no royalties owed to the government, though the government retains royalty free use for a period. Selection to receive SBIR grants also confer a certification effect—acting as a signal to private investors of the technical and commercial promise of the technology.

From the perspective of the government, the SBIR program helps achieve agency missions as well as encourage knowledge-based economic growth.⁶ By providing a bridge between small companies and the federal agencies, especially for procurement, SBIR serves as a catalyst for the development of new ideas and new technologies to meet federal missions in health, transport, the environment, and defense.⁷ It also provides a bridge between universities and the marketplace, thereby encouraging local and regional growth.⁸ Finally, by addressing gaps in early-stage funding for promising technologies, the program helps the

³ NSF, for example, has what is called a Phase II-B program that allocates additional funding to help potentially promising technology develop further and attract private matching funds. As with venture-funded firms, Phase III is likely to include some mix of economically viable and non-viable products, ultimately to be determined by the relevant agency mission requirements or private markets.

⁴ See Reid Cramer, "Patterns of Firm Participation in the Small Business Innovation Research Program in Southwestern and Mountain States," in National Research Council, The Small Business Innovation Research Program, An Assessment of the Department of Defense Fast Track Initiative, C. Wessner, ed., Washington, D.C.: National Academy Press, 2000.

⁵ This certification effect was initially described by Josh Lerner, "Public Venture Capital," in National Research Council, *The Small Business Innovation Program: Challenges and Opportunities*, C. Wessner, ed. Washington, D.C.: National Academy Press, 1999.

⁶ See the presentation of Robert Norwood of NASA in National Research Council, The Small Business Innovation Research Program: Program Diversity and Assessment Challenges, op. cit.,, pp. 95-100.

⁷ See the presentation of Kenneth Flamm in National Research Council, The Small Business Innovation Research Program: Program Diversity and Assessment Challenges, op. cit., pp. 63-67.

⁸ See the presentation of Christina Gabriel in National Research Council, *The Small Business Innovation Research Program: Program Diversity and Assessment Challenges*, op. cit., pp. 131-133.

nation capitalize on its substantial investments in research and development. While SBIR operations and accomplishments are sometimes discussed in general terms, the actual implementation of the program is carried out in agencies with quite distinct missions and interests. There is, therefore, significant variation in program objectives and procedures.

THE NRC ASSESSMENT

Despite its size and 20-year history, the SBIR program has not been comprehensively examined. There have been some previous studies focusing on specific aspects or components of the program—notably by the General Accounting Office and the Small Business Administration. There are, as well, a limited number of internal assessments of agency programs. The academic literature on SBIR is also limited.

To help fill this assessment gap, and to learn about a large, relatively under-evaluated program, several years ago the National Academies' Committee for Government-Industry Partnerships for the Development of New Technologies was asked to review the SBIR program, its operation, and current challenges. Under its chairman, Gordon Moore, the Committee convened government policymakers, academic researchers, and representatives of small business for the first comprehensive discussion of the SBIR program's history and rationale, to review existing research, and to identify areas for further research and program improvements.¹³

The Moore Committee reported that:

- SBIR enjoyed strong support in parts of the federal government as well as in the country at large.
- At the same time, the size and significance of SBIR underscored the need for more research on how well it is working and how its operations might be optimized.

⁹ See the presentation by Joseph Bordogna in National Research Council, The Small Business Innovation Research Program: Program Diversity and Assessment Challenges, op. cit., pp. 123-128.

¹⁰ See for example, GAO, "Federal Research: Small Business Innovation Research Shows Success but Can Be Strengthened," GAO/RCED-92-37, 1992; GAO, "Federal Research: DOD's Small Business Innovation Research Program," GAO/RCED-97-122, 1997; GAO, "Federal Research: Evaluation of Small Business Innovation Research Can Be Strengthened," GAO/RCED-99-114, 1999; GAO, "Survey of Companies Receiving Small Business Technology Transfer (STTR) Phase II Awards Fiscal Years 1995-1997," GAO-01-766R, 2001; and GAO, "Small Business Innovation Research: Information on

Awards Made by DoD in Fiscal Years 2001 Through 2004," GAO-06-565, 2006.

¹¹ Agency reports include an unpublished 1997 DoD study on the commercialization of DoD SBIR. NASA has also completed several reports on its SBIR program. Following the authorizing legislation for the NRC study, NIH launched a major review of the achievements of its SBIR program.

¹² Writing in the 1990s, Joshua Lemer positively assessed the program, finding "that SBIR awardees grew significantly faster than a matched set of firms over a ten-year period." See Josh Lemer, "The Government as Venture Capitalist: The Long-Term Effects of the SBIR Program," Journal of Business 72(2), July 1999. Underscoring the importance of local infrastructure and cluster activity, Lerner's work also argued that the "positive effects of SBIR awards were confined to firms based in zip codes with substantial venture capital activity." These findings were consistent with both the corporate finance literature on capital constraints and the growth literature on the importance of localization effects. For example, see Michael Porter, "Clusters and Competition: New Agendas for Government and Institutions," in On Competition, Boston: Harvard Business School Press. 1998.

¹³ See National Research Council, The Small Business Innovation Research Program: Challenges and Opportunities, op cit.

- There should be additional clarification about the primary emphasis on commercialization within SBIR, and about how commercialization is defined.
- There should also be clarification on how to evaluate SBIR as a single program that
 is applied by different agencies in different ways.¹⁴

Subsequently, at the request of the Department of Defense, the Moore Committee was asked to review the operation of the SBIR program at Defense, and in particular the role played by the Fast Track Initiative. This resulted in the largest and most thorough review of any single SBIR program to date. The study found that the SBIR program at Defense was contributing to the achievement of mission goals—funding valuable innovative projects—and that a significant portion of these projects would not have been undertaken in the absence of the SBIR funding.¹⁵ The Moore Committee's assessment also found that the Fast Track Program increases the efficiency of the Department of Defense SBIR program by encouraging the commercialization of new technologies and the entry of new firms to the program.¹⁶

More broadly, the Moore Committee found that SBIR facilitates the development and utilization of human capital and technological knowledge.¹⁷ Case studies have shown that the knowledge and human capital generated by the SBIR program has economic value, and can be applied by other firms.¹⁸ And through the certification function, which generates additional information for investors, SBIR awards encourage further private sector investment in the firm's technology.

Based on this and other assessments of public-private partnerships, the Moore Committee's Summary Report on U.S. Government-Industry Partnerships recommended that "regular and rigorous program-based evaluations and feedback is essential for effective partnerships and should be a standard feature," adding that "greater policy attention and resources to the systematic evaluation of U.S. and foreign partnerships should be encouraged."

In light of that history, the current assessment mandated by Congress should be seen as a major opportunity to gain an understanding of what is, after all, one of the nation's largest programs for financing early-stage innovation. The legislation focuses on the five agencies that account for 96 percent of program expenditures, although the National Research Council is seeking to learn about the views and practices of other agencies administering the program as well. The mandated agencies, in order of program size, are the Department of Defense, the National Institutes of Health, the National Aeronautics and Space Administration, the Department of Energy, and the National Science Foundation.

¹⁴ Ibid.

¹⁵ National Research Council, The Small Business Innovation Research Program: An Assessment of the Department of Defense Fast Track Initiative, op. cit. See Section III, Recommendations and Findings, p. 32

¹⁶ Ibid, p. 33.

¹⁷ Ibid, p. 33.

¹⁸ Ibid, p. 33.

¹⁹ See National Research Council, Government-Industry Partnerships for the Development of New Technologies, Summary Report, C. Wessner, ed., Washington, D.C.: National Academy Press, 2002, p. 30.

Logic of the Current NRC Study

The current NRC assessment has been structured in three phases, with the first phase focused on fact-finding. A launch conference was a key element in this first study phase in that it:

- Provided agencies an opportunity to describe program operations, challenges, and accomplishments;
- Highlighted the important differences in agency goals, practices, and evaluations carried out within the common framework of the program; and
- Described the evaluation challenges arising from the diversity in program objectives and practice.

This first phase also developed a study methodology, which is a complement of evaluation tools and research strategies. Following review and approval by an independent National Academies panel of experts of this methodology, the second phase implemented the research methodology, gathered the results of surveys and case studies, and developed recommendations and findings.²⁰

The third and final phase involves the preparation of reports on each agency program and the dissemination of the findings. Thus, in addition to its initial conference report, the NRC Committee expects to publish reports evaluating SBIR at each of the five mandated agencies listed above. An additional final report will include the Committee's overall findings and recommendations for the program, as well as a summary of the main points from the individual agency reports.

UNCERTAINTIES IN EARLY-STAGE FINANCING

In the United States today, the beneficial effects of science-based innovations are apparent in almost every arena—from health care and communications to leisure and defense applications. Given that many of these visible successes are products grounded in government-funded research and procurement, there is an understandable desire to ensure that federal policies smooth the path toward commercialization.²¹

This federal role is important, especially as it affects potential investors' perceptions of risk, keeping in mind that commercializing science-based innovations is inherently a high-risk endeavor.²² One source of risk is the *lack of sufficient public information* for potential investors

²⁰ For a description of current NRC program assessment, see National Research Council, Capitalizing on Science, Technology, and Innovation: An Assessment of the Small Business Innovation Research Program, Project Methodology. Access at http://www.nationalacademies.org/gateway/pga/2844.html. The NRC analysis draws on existing reports and data sources, as well as from newly commissioned surveys of award recipients and program managers, and extensive case studies.

²¹ For an overview of the importance of federal contributions to technology development, see Vernon Ruttan, Technology, Growth and Development. An Induced Innovation Perspective, New York: Cambridge University Press, 2001. See also David Audretsch et al., "The Economics of Science and Technology," Journal of Technology Transfer, 27:155-203.

²² See, for example, Lewis M. Branscomb, Managing Technical Risk: Understanding Private Sector Decision Making on Early Stage Technology Based Projects. Lewis M. Branscomb, Kenneth P. Morse, Michael J. Roberts, Darin Boville. Washington, D.C.: Department of Commerce/National Institute of Standards and Technology, 2000.

about technologies developed by small firms.²³ Potential investors seek to learn about the growth potential of small firms, yet in many cases, the entrepreneur – especially in high-technology startups – is likely to better understand the technology and may well foresee its probable application better than potential investors. And even this understanding may not include a competent assessment of commercial potential.²⁴

A second related hurdle is the leakage of new knowledge that escapes the boundaries of firms and intellectual property protection. The creator of new knowledge can seldom fully capture the economic value of that knowledge for his or her own firm. This spillover can inhibit investment in promising technologies for large and small firms—though it is especially important for small firms focused on a promising product or process.²⁵

The challenge of incomplete and insufficient information for investors and the problem for entrepreneurs of moving quickly enough to capture a sufficient return on "leaky" investments pose substantial obstacles for new firms seeking capital. The difficulty of attracting investors to support an imperfectly understood, as yet-to-be-developed innovation is especially daunting. Indeed, the term, *Valley of Death*, has come to describe the period of transition when a developing technology is deemed promising, but too new to validate its commercial potential and thereby attract the capital necessary for its development.²⁶

ROLE OF GOVERNMENT FUNDING IN EARLY-STAGE TECHNOLOGY DEVELOPMENT

Despite these challenges, some firms do find their way through this Valley of Death with financing from wealthy individual investors (business "angels") or, later in the development cycle, from venture capital firms. Recognizing the important role played by these business angels and venture capital firms, academic researchers and others have initiated new research on their impact.²⁷ In this regard, one recent study found that while the ratio of funding provided by venture capital groups to the total funding for R&D has averaged less than 3

²³ Joshua Lerner, "Evaluating the Small Business Innovation Research Program: A Literature Review," in National Research Council, The Small Business Innovation Research Program: An Assessment of the Department of Defense Fast Track Initiative, op. cit. For a seminal analysis on information asymmetries in markets and the importance of signaling, see Michael Spence, Market Signaling: Informational Transfer in Hiring and Related Processes, Cambridge: Harvard University Press, 1974.

²⁴Joshua Lerner, "Public Venture Capital: Rationale and Evaluation," in National Research Council, Small Business Innovation Research: Challenges and Opportunities, op cit.

²⁵Edwin Mansfield, "How Fast Does New Industrial Technology Leak Out?" Journal of Industrial Economics, Vol. 34, No. 2, pp. 217-224.

²⁶See Vernon J. Ehlers, Unlocking Our Future: Toward a New National Science Policy, A Report to Congress by the House Committee on Science, Washington, D.C.: Government Printing Office, 1998. Accessed at http://www.access.gpo.gov/congress/house/science/cp105-b/science105b.pdf.

²⁷See Jeffrey Sohl's 1999 article in Venture Capital, Vol. 1, No. 2, pp. 101-120. Dr. Sohl estimates that of the total populations of business angels and of venture capital funds, each of the two groups invests approximately the same annual amounts in small firms (\$30-40 million), but the funds of business angels are spread over some 50,000 firms, while those of venture capital groups are focused on some 4,000 firms. The typical "deal size" for angels is approximately \$50,000-\$1 million and for venture capital firms \$8-9 million. See also Jeffrey Sohl, John Freeat, and W.E. Wetzel, Jr., "Angles on Angels: Financing Technology-Based Ventures - An Historical Perspective," Venture Capital: An International Journal of Entrepreneurial Finance, 4(4): 275-287, 2002.

percent in recent years, venture capital accounts for about 15 percent of industrial innovations.²⁸

Within the last decade, the number of venture capital firms that invest primarily in small business tripled, and their total investments rose eight-fold.²⁹ This was followed by a sharp contraction in 2000 in the venture capital market, especially for new start-ups as low valuations and a contraction in IPO activity concentrated fund managers' attention on existing investments.

Although business angels and venture capital firms, along with industry, state governments, and universities provide funding for early-stage technology development, the federal role may well be larger than is generally thought. Recent research by Branscomb and Auerswald estimated that the federal government provides between 20 to 25 percent of all funds for early-stage technology development—a substantial role by any measure. (See Figure 1.)

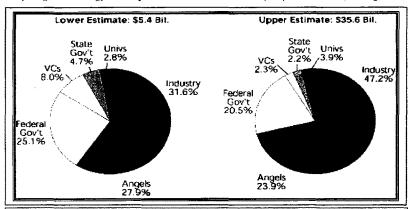


Figure 1. Estimated Distribution of Funding Sources for Early-Stage Technology Development Lewis M. Branscomb and Philip A. Auerswald, Between Invention and Innovation: An Analysis of Funding for Early-Stage Technology Development, Gaithersburg, MD: NIST GCR 02–841, November 2002, p. 23.

This contribution is made more significant in that the government awards address segments of the innovation cycle that private investors often find too risky. Because technology-based firms are a significant source of innovation and competitive advantage for the United States,

²⁸Samuel Kortum and Josh Lerner, 1998. "Does Venture Capital Spur Innovation?" NBER Working Papers 6846, National Bureau of Economic Research, Inc.

²⁹Jeffrey Sohl, <u>http://www.unh.edu/cvr/</u>.

No The authors stress the "limitations inherent in the data and the magnitude of the extrapolations..." and urge that the findings be interpreted with caution. They note further that while the funding range presented for each category is large, these approximate estimates, nonetheless, provide "valuable insight into the overall scale and composition of early-stage technology development funding patterns and allow at least a preliminary comparison of the relative level of federal, state, and private investments." For further discussion of the approach and its limitations, see Lewis M. Branscomb and Philip E. Auerswald, Between Invention and Innovation, An Analysis of Funding for Early-Stage Technology Development, Gaithersburg, MD: NIST GCR 02-841, November 2002, pp. 20-24.

it is important to improve our understanding of how public-private partnerships policies—in this case, innovation awards—can play in encouraging small-firm growth.³¹

The Role of Government Partnerships

Partnerships in general are cooperative relationships involving government, industry, laboratories, and (increasingly) universities, organized to encourage innovation and commercialization. The long-term goal of these public-private partnerships is to develop industrial processes, products, and services, and thereby apply new knowledge to government missions such as improved health, environmental protection, and national security.³²

Overcoming Investment Barriers

A key purpose of public-private partnerships is to help entrepreneurs overcome the financial and other obstacles they face in developing new technologies for the market.³³ In the case of a research consortium, the government can facilitate cooperation among firms in developing pre-competitive platform technologies by providing, for example, matching funds and selective exemptions to antitrust laws.

Innovation awards—another important type of government-industry partnership—are intended to encourage the development of promising technologies that might otherwise be perceived to be too financially risky. As noted above, even the largest firms may not be able to recapture an investment in a technology that "leaks" too soon to too many users.³⁴ Recent assessments of innovation award programs support the view that these government-industry partnerships can help firms overcome barriers to investment for promising, high-spillover technologies.³⁵

Indeed, the National Academies' Moore Committee found that such public-private partnerships "can play an instrumental role in accelerating the development of new

³¹ See National Research Council, Government-Industry Partnerships for the Development of New Technologies, Summary Report, op. cit., passim.

³³ Lewis M. Branscomb and Philip E. Auerswald, Taking Technical Risks: How Innovators, Managers, and Investors Manage Risk in High-Tech Innovations, Cambridge MA: MIT Press, 2001.

^{*}Technological knowledge that can be replicated and distributed at low marginal cost may have a gross social benefit that exceeds private benefit—and in such cases is considered by many as prone to be undersupplied relative to some social optimum. See Richard N. Langlois and Paul L. Robertson, "Stop Crying over Spilt Knowledge: A Critical Look at the Theory of Spillovers and Technical Change," paper prepared for the MERIT Conference on Innovation, Evolution, and Technology, August 25-27, 1996, Maastricht, Netherlands. "See Albert N. Link, "Enhanced R&D Efficiency in an ATP-funded Joint Venture," in The Advanced Technology Program: Assessing Outcomes, C. Wessner, ed., Washington, D.C.: National Academy Press, 2001. For a review of why firms might under-invest in R&D, see Albert N. Link, "Public/Private Partnerships as a Tool in Support of Industrial R&D: Experiences in the United States," Final Report to the Working Group on Innovations and Technology Policy of the OECD Committee for Scientific and Technology Policy, January 1999. For specific reviews of programs such as SBIR, ATP and SEMATECH, see National Research Council, The Small Business Innovation Research Program: An Assessment of the Department of Defense Fast Track Initiative, op. cit.; National Research Council, The Advanced Technology Program, Assessing Outcomes, C. Wessner, ed., Washington, D.C.: National Academy Press, 2001; and National Research Council, Swaring the Future: Regional and National Programs to Support the Semiconductor Industry, C. Wessner, ed., Washington, D.C.: National Academies Press, 2003.

technologies from idea to market."³⁶ It further identified several broad conditions contributing to successful partnerships: As applied to SBIR, these include:

- Industry Initiation: Individual researchers and firms develop proposals in response to
 government solicitations that are fairly broad, or, in some cases, purely at their own
 initiative. This bottom-up, self-selection approach is a source of strength for award
 programs, allowing great flexibility and encouraging diversity.
- Competitive Selection Mechanisms: The SBIR program, while relatively large, remains highly competitive.³⁷ Normally, under 15 percent of Phase I candidates are successful.
- Shared Cost Commitments: SBIR awards can encourage innovation, leverage company investments, attract other sources of capital, and ensure management commitment because awardees retain control of the intellectual property.
- Objective and Ongoing Assessments: Regular evaluations of the partnership programs at the operational and policy levels are needed to ensure effective alignment of the program with current agency goals and needs.

Capitalizing on National Investments in Research

Reaching similar conclusions, a study by the National Academies' Committee on Science, Engineering, and Public Policy found partnerships to be an essential tool in the mix of policies needed to capitalize on the nation's investments in scientific research.³⁸ It observed that partnerships contribute to a relatively open flow from fundamental breakthroughs to first demonstrations to product applications. This openness was seen as a particular strength of the U.S. innovation system. Citing the development of monoclonal antibodies, and the semiconductor technologies underlying personal computers and the Internet as examples, the report identified four conditions favorable for effective commercialization of the fruits of research. These are the presence of:

- Mechanisms for research and capitalization that support cooperation between the academic, industry, and government sectors;
- A strong, diverse national portfolio of science and technology investments;
- A favorable environment for capitalizing on research investments, characterized by strong incentives for innovation and free movement of ideas and people; and
- A skilled, flexible science and engineering human resource base.

The report further noted that nearly all the successful examples of capitalization examined depended on the collaboration of scientists and engineers who had diverse perspectives, time frames, and talents, drawn from the whole web of public, private, and educational institutions. This web of institutions, it said, had become far more complex in recent years, as many large corporations reached outside the firm to rely on universities, suppliers, and subcontractors as sources of research. Similarly, technology-oriented start-ups too small to

³⁶ See National Research Council, Government-Industry Partnerships for the Development of New Technologies: Summary Report, op. cit.

³⁷ The SBIR program now disburses \$2.05 billion in awards annually.

³⁸ The analysis was carried out by the NRC's Committee on Science, Engineering, and Public Policy (COSEPUP). See National Research Council, Capitalizing on the Results of Scientific Research, Washington, D.C.: National Academy Press, 1999.

support basic research programs often depended on close contacts with university researchers.

The report concluded that governments, industries, and universities should continue to experiment with partnerships and consortia, with the goals of conducting mutually beneficial research, invigorating education, and capitalizing on research for the benefit of society. During the partnership phase, industry should share costs and take the initiative in research directions—criteria met by the SBIR program.

ASSESSING SBIR

As noted earlier, the SBIR program has not been comprehensively assessed to date, despite its size and twenty-year history. Even so, there are numerous views of the program that have developed in the absence of credible data and analysis. The current NRC assessment has the potential to contribute to a greater understanding of the program by improving knowledge about its operations, achievements, potential, and constraints based on the evidence it has collected. This knowledge may help illuminate some commonly held opinions about SBIR as well as suggest ways to improve the operation and impact of the program.

Some Contrasting Views of the Program

Some commentators have suggested that the failure rate of SBIR awards is too high, which suggests, in turn, that the program funds R&D of marginal value. This is a challenging point. Measuring the impact and results of an R&D program is intrinsically difficult.³⁹ What constitutes an acceptable failure rate for a program designed to make high-risk, potentially high-payoff investments is, of course, a central question—one that is especially difficult for those with a fiduciary responsibility for public funds. High-risk R&D investments are, indeed, high-risk—project failures in such initiatives are inevitable and not necessarily indicative of program failure.

Still, the question of what an appropriate return on investment in new technologies remains. One benchmark may be the venture capital market, where only about 10 percent of investments in new firms succeed. A key question in assessing SBIR is whether this comparison is appropriate. A hother recurrent question is whether a project or firm failure is indicative of a complete loss on federal investment—as it sometimes is—or if the loss is mitigated by knowledge generated by the SBIR grant that is then transmitted through less direct ways to the overall benefit of society. This second scenario takes into account potential indirect knowledge spillovers that were not a part of the original research design or intent. Consider, for example, the case of a principal investigator who takes the knowledge

³⁹ See National Research Council, Capitalizing on the Results of Scientific Research, Washington, D.C.: National Academy Press, 1999.

⁴⁰ Despite the growing popularity of the idea of "public venture capital" programs, SBIR cannot be considered a venture capital program because awards do not involve equity ownership, management input, or an exit strategy, involving sale of the firm. For a description of a public venture initiative, see the presentation of the CIA's In-Q-Tel by Gilman G. Louie, "In-Q-Tel A 'Nonprofit Venture Capital Fund," in National Research Council, A Review of the New Initiative at the NASA Ames Research Center, C. Wessner, ed., Washington, D.C.: National Academy Press, 2001.

gained from work at a "failed" firm and uses it at a new firm to guide product development in an entirely new market. 41

An additional concern is that SBIR awards might "crowd out" or replace private capital. While theoretically possible, recent work by Bronwyn Hall, Paul David, and Andrew Toole suggests that the overall empirical evidence for "crowding out" is at least equivocal. Litterestingly, there is some positive evidence that programs like SBIR can prompt "crowding in" of private capital. Awards have a "halo effect" that attracts private investors, who see the awards as a certification of technical quality, reducing the uncertainty inherent in early-stage investment. The programs is the stage investment of the control of technical quality, reducing the uncertainty inherent in early-stage investment.

Finally, some object to the SBIR program more broadly as an unwarranted and unnecessary intervention in capital markets. 44 Yet, as noted above, it is widely recognized that capital markets are imperfect with significant gaps (or asymmetries) in information between the potential investor and the prospective entrepreneur. 45 Venture capital markets, in particular, tend to focus on later stages of technology development than SBIR, and venture funds in the aggregate seem to be prone to herding tendencies. The attention of private investors does not necessarily extend to all areas of socially valuable innovation. 46

Perhaps the most significant point to retain from these various perspectives on SBIR is how much uncertainty surrounds early-stage finance in the U.S. economy. As noted, some recent work suggests that the federal role in early-stage firm development is more significant than commonly believed, while also affirming the analytical uncertainty surrounding the funding and development of early-stage firms. Strong affirmations about the "appropriate" role of government support for innovation are not borne out by the history of innovation and industrial development in the United States or, indeed, recent experience.⁴⁷

The Challenge of Establishing Causality

The issue of causality is complex. Awards are given to firms for projects. Yet specific projects funded by SBIR can be difficult to track even within a company. Firms that are

⁴¹ Relatedly, see the description by Duncan Moore of his experience in SBIR-financed work on gradient optics that was not initially commercially successful but that later led to the invention and successful commercialization of the borescope. National Research Council, *The Small Business Innovation Research Program: Program Diversity and Assessment Challenges*, op. cit., pp. 93-94.

⁴² See Paul A. David, Bronwyn H. Hall, and Andrew A. Toole, "Is Public R&D a Complement or Substitute for Private R&D? A Review of the Econometric Evidence," No 7373, NBER Working Papers, 1999.

⁴³ See Maryann P. Feldman and Maryellen R. Kelley, "Leveraging Research and Development: The impact of the Advanced Technology Program: Assessing Outcomes, op. cit.

[&]quot;See, for example, Scott Wallsten, "Rethinking the Small Business Innovation Research Program," in L. M. Branscomb and J. Keller, eds., Investing in Innovation: Creating a Research and Innovation Policy, Cambridge, MA: The MIT Press, 1998, pp. 194-220.

⁴⁵ See Michael Spence, Market Signaling: Informational Transfer in Hiring and Related Processes, op. cit.

⁴⁶ See case studies in National Research Council, The Small Business Innovation Research Program: An Assessment of the Department of Defense Fast Track Initiative, op. cit.

⁴⁷ See the discussion of this question in the Introduction to the review of the Advanced Technology Program in National Research Council, The Advanced Technology Program: Assessing Outcomes, op. cit., and National Research Council, The Small Business Innovation Research Program: An Assessment of the Department of Defense Fast Track Initiative, op. cit.

granted SBIR awards can merge, fail, and change their name before a product reaches the market. In addition, key individuals can change firms, carrying their knowledge of the project with them. In this way, an SBIR investment in one firm may translate into a valuable product from another firm. Especially when the process from discovery to market is long, as is the case for drug development, these transitions are difficult to track.

One way to measure the value of SBIR is to track awards to see if they have resulted (variously) in publications, citations, patents, products, licensing, sales, and increased employment for firms receiving awards. While data relating to these metrics appear to promise information of some significance on SBIR's impact, accurate data on commercial successes can be difficult to gather for a variety of reasons, not least definitional.

The Challenge of Gauging Commercial Success

Given the diversity of agency missions and objectives, commercial success can vary substantially. For example, gauging success in public procurement of SBIR technologies can depend on the nature of the product, the type of research, and its utility for the agency mission. In some cases, the appropriate metric is likely to vary with the specific mission of the agency or sub-unit. For some research questions, the project report itself may constitute the product. For the Department of Defense, one way of measuring commercialization success would be to count the products procured by the agency—although large procurements from major suppliers are more easily tracked than products from small suppliers such as SBIR firms. However, successful development of a technology or product does not always translate into successful "uptake" by the procuring agency, often for reasons having little to do with product quality or its potential contribution to an agency's mission.

Even promising research does not always move toward the market in a linear fashion. Sometimes research enabled by a particular SBIR award takes on commercial relevance in new unanticipated contexts. Duncan Moore of the University of Rochester recounts for example that his SBIR-funded research in gradient index optics was initially a commercial failure when an anticipated market for its application (in picture phones) did not emerge. However, the technology later found substantial commercial success in the boroscope, a device used to look inside materials and structures. This story illustrates that today's commercial dead end could well be a key to tomorrow's market success.

While the concept of "commercial" at the Department of Defense most often relates to the use of a new product or process by the government, the concept more conventionally refers to the means by which a new product or process—provided by a viable business enterprise—enters the market on an independent, third party, competitive basis. These differing interpretations also reveal the differing pathways to commercialization. For some products, this path is akin to a long, complex, winding, and uncertain road. For others, the pathway is more immediate with visible linkages to mission, industrial, and commercial applications.

The Need for Realistic Expectations:

An assessment of SBIR must be based on an understanding of the realities of the distribution of successes and failures in early-stage finance. As with most early-stage finance,

SBIR awards are characterized by a highly skewed distribution of successes. This includes a few genuinely large successes that generate returns that would cover, in themselves, the cost of the entire program. For example, Science Research Laboratory Inc has reported over a billion dollars in sales from a new technology that increased the number of circuits on a computer chip by thirty percent. Similarly, Digital System Resources' technology significantly improved the computing power of sonar technology, leading to its adoption across the U.S. submarine fleet. Below these star performers are a number of more modest successes, followed by a large number of awards that had produced few or no results, he said. Given this skew, a purely random sample of individual project outcomes is likely to yield an imbalanced assessment of the SBIR program.

Compared to What?

Appropriate expectations for success, or indeed failure, is sometimes overlooked in assessing SBIR. Senior executives from pharmaceutical companies have observed that the failure rate for the biotechnology industry, form target identification to product launch, is about 90 percent. This holds true even in the best of circumstances and even for large companies that had invested billions of dollars in research and development. Venture capital firms, which typically fund more articulated and market-proximate proposals than SBIR, report similar rates of failure. It is against these comparisons that SBIR's awards to new firms should be compared.

In short, when we set metrics for SBIR projects, it is important to have realistic expectations as to what would constitute success and what rate of success we should expect. Some commentators criticize SBIR for not having enough successes. Yet high success rates could imply that the SBIR program does not have a sufficiently risky portfolio: Using success rates alone can be a dangerous metric for assessing SBIR because it can encourage little or no risk taking, obviating, in turn, the advantage of small awards to explore promising ideas—a key feature of the SBIR program.

Concluding the Assessment

The NRC study of SBIR, chaired by Jacques S. Gansler of the University of Maryland and carried out by a distinguished committee, continues to progress. The research phase is complete and the Committee is now assessing the data it has collected and its meaning in terms of program achievements and challenges. One of the encouraging things to which we believe the NRC study has in fact contributed has been the development of an assessment culture among the agencies' SBIR programs. During our study, there has been considerably more attention to program refinement and efforts to assess outcomes from agencies that had previously not conducted such assessments. Partly as a result of these initiatives, the SBIR program continues to evolve and contribute to agency missions. We look forward to bringing you the results of our surveys, case studies, and analysis in the not-too-distant future.

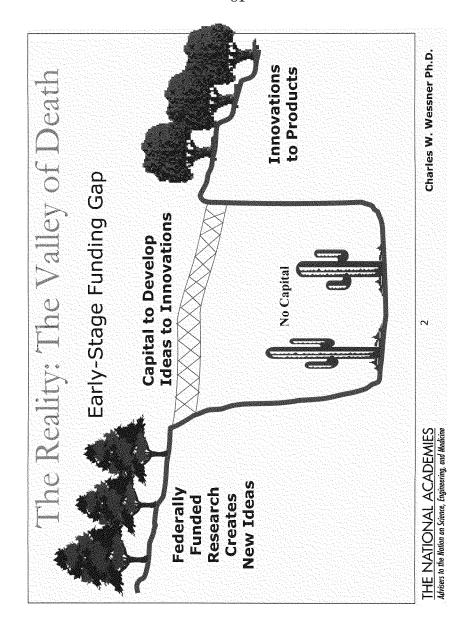
⁴⁸ See the conference presentation of Gail Cassell in National Research Council, The Small Business Innovation Research Program: Program Diversity and Assessment Challenges, op. cit.

The Myth of Perfect Markets

- U.S. Myth: "If it is a good idea, the market will fund it."
- Potential Investors have less than perfect knowledge, especially about innovative new
- "Asymmetric Information" leads to suboptimal This means that it is hard for small firms to obtain funding for new ideas investments
- Development of new technologies within an economy is not automatic I
- Markets do not necessarily allocate resources perfectly Technology trajectories are not pre-ordained

THE NATIONAL ACADEMIES Advisers to the Nation on Science, Engineering, and Medicine

Charles W. Wessner Ph.D.



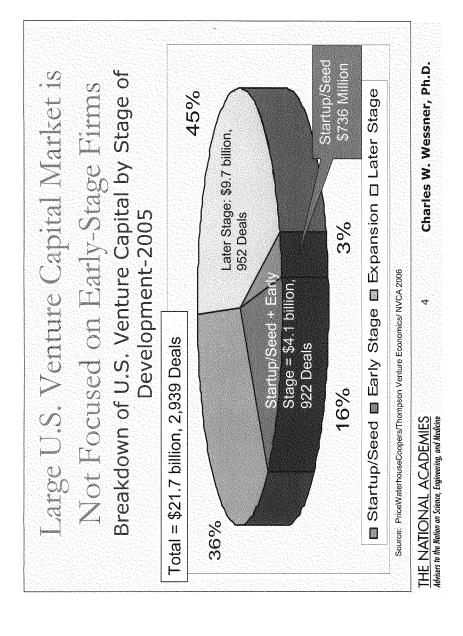
The Myth of U.S. Venture Capital Markets

- Myth: "U.S. VC Markets are broad & deep, thus there is no role for government awards"
 - Reality: Venture Capitalists have
- Limited information on new firms - Prone to herding tendencies
- development
- Focus on later stages of technology
- Most VC investors seek an early exit
- Large U.S. Venture Capital Market is Not Focused on Early-Stage Firms ******

See the current Funding break out

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Charles W. Wessner PhD



SBIR Concept

- · Focused on Government and Societal needs
- Health, Security, Environment, & Energy
- Industry-Initiated Proposals to meet Government needs—Bottom up, not top-down
 - 2-Phase program
- Encourages experimentation while screening out bad ideas
- "Set-aside" funding
- A regular and consistent source of early stage funding
- SBIR funds addresses diverse agency objectives
 - Program ownership rests with many agencies
- Commendable flexibility-- no "one-size-fits-all" approach

THE NATIONAL ACADEMIES
Advisers to the Nation on Science, Engineering, and Medicine

Charles W. Wessner Ph.D.

The Expectations Challenge: "Compared to What?"

- Possible Benchmarks for Results
- − 90% Failure rate in the Bio-pharma industry
- ~90% "Failure" rate for Private Venture Capitalists
- Assessment of SBIR must be based on the realities of Early-Stage Finance
- A number of more modest successes

- High skew with few genuinely large successes

- A significant number of projects will not succeed

THE NATIONAL ACADEMIES Advisors to the Nation on Science, Engineering, and Medicine

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Charles W. Wessner, Ph.D.

Chair SNOWE. Thank you, Dr. Wessner. That was a very interesting presentation, and it certainly speaks to the value of the program that we obviously, as you say, should be building on.

Mr. Watson?

Senator KERRY. Sounds like you have already done your report. [Laughter.]

Dr. WESSNER. Well, we have done these, sir.

STATEMENT OF EUGENE WATSON, PROGRAM MANAGER, WYOMING SBIR/STTR INITIATIVE

Mr. WATSON. Well, thank you, Chuck, and I rest my case.

[Laughter.]

Mr. Watson. However, I will take up my 5 minutes. Although, as Senator Enzi has said, I am a consultant to the University of Wyoming Research Office, the observations and opinions I am

going to express today are my own.

I appear before you as a confessed but unrepentant serial entrepreneur. Over the past five decades, I have participated as a founder in the formation and launch of eight technology-based start-up companies, the most recent three receiving seed capital from the SBIR program.

I have a short list of recommendations to further improve the program, including Senator Vitter's and Senator Bayh's proposals to increase the funding over the next 5 years, and adjusting the aware guidelines to keep pace with inflation. But due to time constraints, I will limit my comments to two critical areas: one is the

effect, and the other is the cause.

It is my conviction that a major threat is looming on the horizon in the form of S. 1263, the Save America's Biotechnology Innovative Research, or SABIR, Act. This proposed legislation has been characterized by a former chief counsel for advocacy at the Small Business Administration as the first effort in the 53-year existence of the SBA to redefine "small business" to include large businesses—an ominous slippery slope indeed. S. 1263 is devised solely to benefit businesses owned and controlled by large venture capital organizations, permitting them for the first time to participate in the SBIR program—in my opinion, a devastatingly bad idea. It abandons Congress' core definition of a small business established over a half-century ago, to wit: "A small business is one that is independently owned and operated." Dozens of Federal laws and regulations are based on this clear and concise concept. Once an exception to this longstanding common-sense principle is adopted, others will surely follow.

Further, the assertion that innovative biotechnology R&D is threatened and needs to be saved is unsupported. Total public and private biotechnology R&D spending this year will approach \$100 billion. Contrasting this amount with the 2006 SBIR budget of \$2.2 billion reveals the futility of assigning the role of savior to the

SBIR program, even were one needed.

But there is more. The implication that the SBIR program has been off limits to venture capital is just wrong, as untrue as the widely circulated misrepresentation that VC-owned companies, previous SBIR eligible, are now disenfranchised. With all due respect to those of differing views, let me be very clear. Companies owned and controlled by large organizations, including venture capital companies, have never been eligible for the SBIR competition. Companies with minority venture capital backing, however, have always been eligible, and a recent GAO report reveals that since 2002, an increasing number of SBIR awards have been made to these VC-backed firms. At NIH, such firms generally receive larger awards and a larger total share of SBIR funds. And VC-backed firms are receiving an increasing share of NIH's total SBIR dollars, up from 14 percent in fiscal year 2001 to 21 percent in fiscal year 2004. Clearly, SBIR funding for VC-backed companies, at least at the NIH, is robust and growing.

This trend, however, raises troubling issues. In many respects, the goals of the SBIR program are at odds with the priorities of the typical venture capital organization. SBIR provides seed capital to high-risk start-up companies, whereas VC investments are risk averse. And although often professing to be the funding source as the start-up gazelles of tomorrow, the facts tell a different story. According to the PricewaterhouseCoopers Money Tree report, over the past decade VC investment in start-up companies has gone

from 20 percent to less than 2 percent.

Equally troubling to this rural-State resident is the geographic concentration of VC investments. Money Tree reports that in first quarter 2005 nearly 60 percent of VC funds went to two States— California and Massachusetts, as we have heard from Senator Kerry. Ten States received 85 percent, with 15 percent shared by the remaining 40 States. Fourteen States received no venture capital whatsoever. I note that 10 of the 18 members of this committee represent States receiving either only one or no VC investment during this period.

From these data, it is clear that as VC participation increases, the little guys, especially those from rural States, will be crowded off the playing field. SBIR is, after all, a zero-sum game.

The tensions between SBIR and venture capital are numerous. Venture capital is risk averse; SBIR is indifferent to risk. Venture capital is inaccessible to start-ups; SBIR is congenial to start-ups. Venture capital is impatient; SBIR has no time constraints. Venture capital is geographically and demographically selective; SBIR has no geographic or demographic bias. Venture capital is technology focused; SBIR is open to all innovative concepts.

Given these polar opposites of missions and priorities, it is clear that the goals of the SBIR program will be seriously compromised by allowing unlimited access to VC-owned and -controlled firms, a serious, unintended consequence of adopting the SABIR legislation.

Now, as to cause, it is my firm belief that the issue of allowing VC-owned companies unlimited access to SBIR funds has its origins in the recently established practice at the NIH of exceeding award guidelines, often by millions of dollars. An important component of the genius of the SBIR program is to provide award amounts sufficient to enable small businesses to develop their innovative concepts while at the same time capping the awards at a level below the threshold of interest of large organizations, such as venture capital companies. That this strategy was effective is proved in the breach. Only when NIH award levels began to routinely exceed the legislative guidelines did SBIR funding become a

target of VC-owned and controlled companies. Awards exceeding the guidelines now account for more than 70 percent of the NIH SBIR dollars.

I strongly urge this committee, through its oversight function, to work with the SBA and the NIH to bring SBIR awards back into compliance with the legislative guidelines. Doing so will resolve critical issues that are before this committee today.

Thank you, Madam Chairman, for allowing me to speak.

[The prepared statement of Mr. Watson follows:]

Testimony

Of

Eugene (Gene) Watson Red Ladder Ranch Centennial, Wyoming 82055 307-742-7162 ewatson@wyoming.com

Senate Committee on Small Business and Entrepreneurship

July 12, 2006

S. 1263 and related Small Business Innovation Research (SBIR) Program issues

Madam Chair and Members of the Committee, thank you for allowing me to appear here today.

I am Eugene Watson, currently an SBIR consultant to the University of Wyoming Research Office and to the Wyoming Business Council, the state's economic development organization. However, the observations and opinions I will present to you this moming are entirely my own.

I appear before you as a confessed but unrepentant serial entrepreneur. Over the past five decades, I have participated as a founder in the formation and launch of eight technology-based start-ups. The largest, a \$600 million enterprise with a market cap of over \$1 billion, celebrated its 40th anniversary this year. The most recent three of these start-up ventures received seed capital funding from the SBIR program. In the process of being principal investigator on four Phase I and four Phase II SBIR projects, I was converted from a skeptic to a staunch SBIR program advocate. I learned hands-on that this is a federal program that really works as it was originally intended, and has done so for nearly a quarter century. I am here to urge you to resolutely protect the integrity of this most successful program so that it can continue to be a major component in the nation's effort to stimulate innovative entrepreneurship.

Although I have a short list of recommendations to further improve the SBIR program, for example, adjusting the award guidelines to keep pace with inflation, due to time limitations, I will restrict my comments this morning to a discussion of a major threat to the program that is looming on the horizon in the form of S.1263, inappropriately titled the 'Save America's Biotechnology Innovative Research Act' or 'SABIR Act'. This legislation has been characterized by a former chief counsel for advocacy at the Small Business Administration (SBA) as the first ever legislative attempt to redefine 'small business' to include large businesses - an ominous slippery slope indeed. In essence, the SABIR Act will allow businesses that are majority-owned and controlled by large businesses to compete against the nation's thinly capitalized small business sector for the 2.5% of federal R&D funds reserved for them by the SBIR program. This Act is devised solely to benefit businesses owned and controlled by venture capital organizations, allowing them, for the first time, to participate in the SBIR program - in my opinion, a devastatingly bad idea. It abandons Congress' core definition of a small business established over a half century ago: 'A small business is one that is independently owned and operated'. Dozens of Federal laws and regulations are based on this logical, clear and concise concept.

The assertion that innovative biotechnology R&D is threatened and needs to be saved is not supported by the facts. A recent PriceWaterhouseCoopers Money Tree Report lists 4Q05 venture capital investment in the biotechnology sector as exceeding \$1 billion; \$4 billion annualized. The FY06 NIH R&D budget is \$28 billion, and total annual U.S. funding for biotechnology R&D across all other organizations, public and private, is certainly in excess of \$50 billion. Contrasting

these expenditures with the SBIR FY06 budget of \$2.2 billion for the eleven participating federal agencies reveals the futility of assigning the role of savior to the SBIR program, were one needed.

But, there's more - the implication that the SBIR program has been off-limits to venture capital participation is wrong, just as untrue as the widely circulated canard that VC-owned companies, previously SBIR eligible, are now disenfranchised. Let's be clear - companies owned and controlled by large organizations, including venture capital partnerships, are not now and have never been eligible for the SBIR competition. Companies with minority venture capital backing have always been eligible to participate in the SBIR competition. And, as of 2005, businesses majority-owned and controlled by venture capital organizations have also become eligible, providing the parent is itself eligible. A Government Accountability Office (GAO) report released in April of this year reveals that since 2002 an increasing number of SBIR awards have been made to firms that have received venture capital. At NIH, such firms have generally received larger awards and a larger total share of available SBIR funds than those companies not VC-backed. And, from FY01 to FY04, the average NIH Phase II award granted to VC-backed firms increased by more than 70% from \$860,000 to \$1.5 million, double the maximum of \$750,000 set by the program guidelines. As a result, VC-backed firms are receiving a greater share of NIH's total SBIR dollars each year – an average of 21% in FY04, up from 14% in FY01. Clearly, SBIR program participation by VC-backed companies, at least at NIH, is robust and growing.

However, to this and many other observers, this trend raises some troubling issues. In many respects, the goals of the SBIR program are at odds with the priorities of the typical venture capital organization. For example, SBIR provides seed capital to high-risk start-up companies whereas VC investments are almost exclusively directed to safer later stage deals. This outcome is not surprising in view of the VC's value proposition to their investors of 'minimize risk, maximize return'. And, although often professing to be the funding source of the start-up companies that will become the gazelles of tomorrow, the facts tell a different story. According to Money Tree, VC investment in start-up companies has, over the past decade, gone from about 20% of distributed funds to less than 2%. As VC-backed firms take an increasing share of SBIR funds, one is provoked to ask 'where will the nation's technology-based start-up ventures find replacement seed capital?'.

Equally troubling, particularly to this rural-state resident, is the geographic and demographic concentration of VC invested capital. A recent Money Tree report reveals that in 1Q05, nearly 60% of VC investments went to two states, California and Massachusetts. The top ten states received 85% of total VC funding with the remaining 15% shared by forty states. Fourteen states received no venture capital whatsoever. As a sidebar, I note that ten of the eighteen members of this

committee represent states receiving either one or no VC investment during this period – and this geographic inequality continues to grow.

From these data, it is clear that as VC participation in the SBIR program increases, the little guys, especially those from rural areas, will be crowded off the playing field as it becomes increasingly tipped in favor of VC-backed companies.

The tension between SBIR seed capital and venture capital is dramatic and growing. Venture capital is risk averse; SBIR capital is wide open to risk. Venture capital is inaccessible to start-ups; SBIR is congenial to start-ups. Venture capital, having a five year timeline from entry to exit, is impatient; SBIR capital can be recurring with no time constraints. Venture capital is geographically and demographically concentrated; SBIR capital has no geographic or demographic bias. Venture capital is herd-like (telecom yesterday, nano and biotech today, who knows tomorrow); SBIR is always open to all innovative concepts.

Given these dramatic opposites of missions and priorities, this question must be addressed, "Are the goals of the SBIR program more or less likely to be achieved by allowing an unlimited VC presence on the SBIR playing field?"

In closing I would like to make an urgent appeal to this committee. It is my conviction, as well as that of a number of well-informed observers, that the controversy over allowing VC-owned companies unlimited access to SBIR funds has its origins in the now routine and growing practice at the NIH of exceeding the SBIR program award guidelines, often by millions of dollars. An important component of the genius of the SBIR program as originally conceived was to provide award amounts sufficient to enable small businesses to develop their innovative concepts while at the same time, capping the awards at a level below the threshold of interest of large organizations such as venture capital companies. That this strategy was effective is proved in the breach - only when NIH award levels began to routinely exceed the legislated guidelines did SBIR funding become a target of VC-owned and controlled companies. According to the GAO report, awards above the guidelines now account for more than 70% of NIH's SBIR dollars. I strongly urge this committee, through its oversight function, to work with the NIH to bring their SBIR awards back into compliance with the legislated guidelines. Doing so will begin the process of resolving some of the critical issues that I and others bring before this committee today.

Thank you, Madam Chair, for providing me with this opportunity to testify.

Chair Snowe. Thank you, Mr. Watson. Dr. Squillante.

STATEMENT OF DR. MICHAEL SQUILLANTE, CHAIRMAN, SMALL BUSINESS TECHNOLOGY COUNCIL, NEW ENGLAND INNOVATION ALLIANCE

Dr. SQUILLANTE. Thank you, Madam Chair, Senator Kerry. I appreciate the opportunity to speak at the committee this morning. I am kind of nervous. This is my first time doing this, it is certain.

tainly exciting.

I am vice president of research at Radiation Monitoring Devices, Incorporated, in Watertown, Massachusetts. At RMD we perform research on nuclear, biochemical, optical, and magnetic sensors, and we manufacture products based on these sensors. In the last few years, we have begun to apply our high-performance sensors to

homeland security applications.

I am also the chairman of the SBTC, and it is the SBTC that I am representing here today. SBTC is the Nation's largest non-profit organization for high-technology businesses. It is a council of the National Small Business Association, which is the oldest advocacy organization for small businesses in the country, which serves over 150,000 companies. Since its founding in 1995, SBTC has been very involved in SBIR issues. More than 300 current members of SBTC have received SBIR awards. No other organization represents more SBIR companies than SBTC.

SBIR has been extremely successful. Over the past 25 years, it has yielded over 45,000 patents, tens of billions of dollars of economic activity, and has solved thousands of technological problems for Federal agencies. The technologies that are invented and developed under SBIR are saving lives on the battlefield and saving lives in the operating room. Technologies are improving the quality

of life of many millions of Americans.

Today, more than half of the scientists and engineers employed in the private sector are employed by small technology companies. And as mentioned by Chair Snowe, they produce 13 times more patents per employee than the patent-producing large corporations.

It is this tremendous success of SBIR which brings me here today. It is an important program, it is working, and we need to keep it working in the future. Congress recognized the need to support small companies which have the flexibility, the talent, the innovation, and the creativity to solve problems when it enacted the SBIR law 25 years ago.

Also, in regard to the SBIR, I would like to take the opportunity and SBTC would like to take the opportunity to thank you again for further improving the SBIR program with the pilot program, which is already having an effect in trying to improve the transition of technologies into use by the Department of Defense.

Also, as was mentioned, the reauthorization is coming soon. This meeting will be a good first step to taking stock of the program, examining what is working well, looking at what needs improvement, and determining what should not be changed in the program.

SBIR is successful because it funds—as we have heard, it funds small, high-risk, high-payoff, early-stage research. It does not try

to pick the next blockbuster product. It tries to fund innovative re-

search which will solve agency problems.

The SBIR program is transparent and extremely competitive. It proceeds through the natural path of R&D: a small amount of funding for proof-of-concept research, further funding for further development and prototype development, and then finally it moves on to Phase III and commercialization. It does a good job of protecting intellectual property rights of small businesses, and it recognizes the parts of the innovation process that small high-tech companies do really well.

But I am here because of a serious concern that there are proposals to make fundamental changes in the SBIR program, and the heart of this is whether or not large venture capital firms will be allowed to participate in a small business program. There are other larger program that venture capitalists can participate in, including at the NIH, which are larger and have more money than the SBIR program and which do not have restrictions on the size of the

corporations that participate.

But even in the SBIR program, venture-backed firms are receiving more than 20 percent of NIH funding. The number is not 0 percent. Currently, venture capitalists of any size that control less than 49 percent of a firm can participate in the SBIR program. If the venture capital meets the statutory guidelines of SBA and SBIR, they can control more than 49 percent.

The proponents say this change is necessary. We disagree. Not only is this change not necessary, it will have significant detrimental effects on the SBIR program. SBIR stands for "Small Business Innovation and Research." The proposed changes will take the "small" out of SBIR, and it will take the "innovation" out of SBIR. We believe that if these changes are implemented, it will make

We believe that if these changes are implemented, it will make awards at NIH less competitive and less transparent. It will undermine the character of the Phase I awards as high-risk, early-stage research. It will also, because of the size of the awards, dramatically reduce the total number of awards that NIH can make, making it that much harder. One in 11 Phase I awards are issued now. It will be much worse if these changes are made. It will inexorably shift the NIH focus away from new cutting-edge innovation and toward research to solving problems which have mass markets. It will crowd out many, if not most, of the small life science and biotechnology companies whose innovations are the key to the future health of the Nation. It also goes against the strong preferences of the vast majority of small companies that are participating in the SBIR program now, including many biotechnology companies.

SBTC had a poll where we polled 2 years' worth of NIH award winners, and of those responding, 90 percent were opposed to these

changes.

We do understand that the venture capital firms have an important function and do critically important work. SBTC does not stand for Small Business Innovation Research Council. It stands for the Small Business Technology Council. We are willing to work, and we do work with anyone who has an interest in Federal R&D. We will work with the agencies, we will work the venture capital firms, we will work with their representatives. But we will not work with them to destroy the SBIR program.

For 25 years, it has been the intent of Congress to capture the talent, creativity, innovation, and flexibility of small technology companies to efficiently and quickly solve technological problems. The costs to the Government of a scientist in a small company is less than 10 percent of the cost of an engineer or scientist at a large company. It is an extremely efficient, fast way to get research done

Again, please do not take the "small" out of SBIR and please do not take the "innovation" out of SBIR.

Thank you.

[The prepared statement of Dr. Squillante follows:]



Testimony of

Michael Squillante, Ph.D.

Vice President, Research RMD, Inc. Watertown, MA

And Chairman of the Board Small Business Technology Council

BEFORE THE COMMITTEE ON SMALL BUSINESS AND ENTREPRENEURSHIP UNITED STATES SENATE

Washington, D.C.

"Strengthening the Participation of Small Businesses in Federal Contracting and Innovation Research Programs"

July 12, 2006

Small Business Technology Council 1156 15th St. NW, Suite 1100 Washington, DC 20005 (202) 659-9320 Fax: (202) 872-8543 <u>www.sbtc.org</u>.

SBTC, the nation's largest association of small, technology-based companies in diverse fields, is proud to serve as the technology council of the National Small Business Association, the nation's oldest nonprofit advocacy organization for small business, serving more than 150,000 small companies throughout the United States.

Madam Chair Snowe, Senator Kerry, members of the Committee, good morning. I am Michael Squillante, Vice President of Research of Radiation Monitoring Devices, Inc., in Watertown, Massachusetts and Chairman of the Small Business Technology Council, the technology council of the National Small Business Association. Thank you for inviting me to appear here.

Radiation Monitoring Devices was founded in 1974 to perform research on high performance sensors, which now includes nuclear, optical biochemical and magnetic sensors. RMD also develops and manufactures commercial products based on these sensors for medical and industrial use. Presently RMD's research is focusing on the next generation of instruments for cancer diagnosis, homeland security and nondestructive testing.

The Small Business Technology Council was founded in 1995 to represent small, technologybased firms. Today such companies employ over half of the nation's scientists and engineers, and produce about 13 times more patents per employee than large patenting firms.² These patents are twice as likely as large firm patents to be among the one percent most cited in scientific and technical literature and in subsequent patent applications.3 Small firm innovation is twice as closely linked to scientific research as large company research, on average, and is thus substantially more "high tech" or "leading edge."4

By almost all objective accounts, including studies by the Government Accountability Office⁵, the National Academy of Engineering⁶, and the National Academy of Sciences⁷, the federal government's most successful effort to encourage and sustain these smaller technology companies has been the Small Business Innovation Research (SBIR) Program.

Progenitor of an astonishing 45,000 patents and tens of billions of dollars in economic activity, this remarkable Program is coming up for re-authorization by Congress soon. We hope that today's hearing marks the beginning of a comprehensive examination of SBIR by this

Science and Engineering Indicators 2006, National Science Foundation. See www.nsba.biz/docs/tibbetts_sbir_reauthorization.pdf

Frequently Asked Questions, U.S. Small Business Administration, June 2006, www.sba.gov/advo/stats/sbfaq.pdf

³ Small Serial Innovators: The Small Firm Contribution To Technical Change, CHI Research, Inc., under contract to the U.S. Small Business Administration, March 2003, www.sba.gov/advo/research/rs225tot.pdf.

Federal Research: Assessment of Small Business Innovation Research Programs, GAO Report RCED89-39, January 23, 1989; Federal Research: Small Business Innovation Research Program Shows Success But Could Be Strengthened, GAO Report T-RCED 92-3, October 3, 1991; Federal Research: Interim Report on the Small Business Innovation Research Program, GAO Report 95-59, March 8, 1995; Federal Research: Observations on the Small Business Innovation Research Program, GAO Report RCED 98-32, April 17, 1998; Federal Research: Observations on the Small Business Innovation Research Program, GAO Report GAO-05-861-T, June 28,2005.

Small Business Innovation Research Program: Challenges and Opportunities, Board on Science, Technology and Economic Policy,

National Academies of Science and Engineering, 1999.

¹ Conflict and Cooperation in the National Competition for High Technology Industry, National Academy of Sciences, 1996; SBIR: Assessment of the Department of Defense Fast Track Initiative, STEP Board, National Academies of Science and Engineering, 2000. Another National Academy of Sciences study of the SBIR Program is ongoing, with a final report expected late in 2006.

Committee, as well as timely re-authorizing legislation. In that light, we commend to the Committee a recent analysis of SBIR by Dr. Roland Tibbetts, the "father" of the Program.⁸

Five Principles

SBTC believes that SBIR owes its success to five central principles.

- 1. The SBIR Program does not "pick winners" that it foresees as "creating new industries" or generating blockbuster performance in the private sector. SBIR contracts are awarded to meet the federal government's own research needs, as stated in published research solicitations. While SBIR technologies that go beyond Phase 1 are expected to be commercializable, neither the federal government nor the SBIR Program Managers attempt to guess which technologies will spawn the "great industries of the future."
- 2. The contract award process is *transparent and competitive*. Any small business may submit a proposal attempting to address the research needs that the government has publicly described. But a scientifically rigorous and equally transparent evaluation process helps assure that only the most promising proposals receive awards.
- 3. The SBIR Program is structured into "Phases" that align with the natural evolution of an innovation through research and development. Phase 1 SBIR Awards aim at the "blank sheet of paper" stage of research developing and proving theoretical technological solutions to problems. Phase 2 Awards move these proven solutions along toward working prototypes. And Phase 3 Awards shift the work toward the "real world" through commercialization whether by having the government itself purchase the products (as agencies like the Defense Department do) or by having the private sector purchase and diffuse them to meet public needs (as agencies like the National Institutes of Health do).
- 4. The SBIR Program is designed to and generally does carefully protect the intellectual property rights of the scientists and inventors that it seeks. That protection assures a continuing flow of the small business community's and many of the nation's top scientists and technologists into innovation challenges that the federal government faces. Yet it avoids both the direct costs of a growth in federal employment and the indirect costs of removing these talented individuals from the private sector.
- 5. Perhaps most importantly over the long run, the SBIR Program is built on a recognition of the different research styles and capabilities of large and small businesses. At exactly the early stages of R&D where small companies have historically been the most productive producers of technological breakthroughs, they, and only they, can access SBIR research awards. These small companies are not required to compete with universities or large businesses for their contract awards. They compete only with one another, and on a level playing field. At the later stages of R&D where large company financial support, manufacturing expertise and marketing muscle is vital corresponding to Phase 3 of SBIR such companies are welcomed into the Program. Indeed, they are indispensable to its success.

These principles can help us put today's discussion in context.

⁸ This paper can be accessed from the SBTC website, at www.nsba.biz/docs/tibbetts_sbir_reauthorization.pdf
⁹ See William J. Baumol "Entrepreneurship, Innovation and Growth: the David-Goliath Symbiosis", Journal of Entrepreneurial

See William J. Baumol "Entrepreneurship, Innovation and Growth: the David-Goliath Symbiosis", Journal of Entrepreneurial Finance and Business Ventures, Vol. 7, Issue 2, Fall 2002, pp. 1-10.

Turning now to the proposed change in the SBIR Program, I will suggest some insights based on SBTC's experience with the Program, and that of my company.

SBTC's Background

More than three hundred of SBTC's member companies that have won SBIR contract awards from different agencies of the federal government. So have scores of former SBTC member companies that have been merged or acquired by other firms. No organization in the United States represents as many current and former SBIR contract awardees. Using this "intellectual capital," SBTC has been closely involved in the development and reauthorizations of the SBIR Program for over a decade. SBTC's Executive Director was a principal architect of the original SBIR legislation in 1982.

RMD's Experience with SBIR

With a major assist from SBIR contract awards at key points in our history, my company – RMD – has grown from 12 employees to 80 and has spun off six new high technology companies. More importantly, SBIR funding, and in particular SBIR funding from the National Institutes of Health (NIH), has allowed us to carry out research and development that improves the quality of life of tens of thousands of people in a many ways, from making possible better surgical outcomes and faster post operative recovery to helping insure homes are free of lead which still affects hundreds of thousands of children in the United States. For example, an NIH SBIR grant carried out by RMD in collaboration with Dr. David Stump at the Wake Forest University School of Medicine changed the way open heart surgery is performed, resulting in an order of magnitude reduction in the incidence of stroke following surgery.

Our Concerns

I am here today because of SBTC's and my company's serious concern that some proposals for fundamental change in this vital small business program will make it much harder for small firms to produce significant life science innovations in the future.

Venture capital companies are the crux of the issue.

Currently, VC's of any size may control up to 49% of SBIR companies. And VC's that are *small* by SBA and SBIR statutory standards (fewer than 500 employees, including affiliates and subsidiaries) may control up to 100% of SBIR companies.

The dispute centers on what *large* VC's will be permitted to do. Some elements of the biotechnology and venture capital industries want to allow venture capital companies that are *large* by SBA and SBIR statutory standards to own or control small companies that receive SBIR contract awards.

Such an action would breach the SBA affiliation rule – something that has never occurred in the fifty-three year history of the Small Business Act and the Small Business Administration. It would also breach SBIR's statutory definition of a small business, established by Congress nearly 25 years ago and ratified at least four times since.

Proponents say that this dramatic change is necessary to assure small life science companies with the outside capital they need to grow.

We disagree. Not only is it unnecessary; it is detrimental to SBIR.

We believe this change, if implemented, would:

- 1. Make SBIR awards at NIH both less competitive and less transparent.
- 2. Undermine the character of NIH's Phase 1 Awards as early-stage R&D.
- Reduce, probably dramatically, the number of NIH SBIR awards and the number of recipient companies.
- Short-circuit SBIR Phase 3, Congress' intended locus for partnerships between large and small companies.
- Inexorably shift the NIH SBIR focus away from a pure expression of the agency's own research needs and toward the preferences of large venture capital company investors.
- Crowd out many small life science and biotechnology companies with important innovations.
- 7. Go against the strong preferences of current SBIR awardees at NIH.
- 8. Duplicate the funding that is already available through other NIH channels to biotechnology firms that are owned or controlled by large VC's.
- 9. Further concentrate SBIR awards in a few states.
- 10. Raise questions about whether SBIR is truly a small business program.
- 11. Create dangerous legal precedents that could threaten not only the SBIR Program, but most other federal small business programs.

Competition

The selection of SBIR awardees at NIH is based on a scoring system. Proposals score well when they include items like preliminary research results, well-credentialed teams, and connections to other ongoing research related to the topic. A company with access to deep-pocketed VC's will be able to afford all this and more. Not only can such a company develop preliminary research, assemble impressive teams, and gain access to related research. It can also afford to submit multiple proposals for each research topic – and to assemble all of its proposals into far more polished packages than small start-up companies can afford. In time, these advantages will sharply tilt the playing field toward SBIR proposals backed by large VC's. The companies that are crowded out will be exactly those "diamonds in the rough" that the SBIR Program was intended to identify and nurture. Moreover, these large VC-backed firms are primarily interested in high-dollar awards that NIH has been making in violation of the SBIR Program Guidelines. Since the dollars available in the SBIR Program are capped, these high-dollar awards are reducing the total number of SBIR awards available. Insert large VC's into this situation and smaller companies will get a "double whammy." Not only will they be competing against rivals financed by large VC's, but they will also be competing for fewer awards.

¹⁰ According to GAO, over 50% of NIH's recent SBIR awards exceeded the Program Guidelines published in the Federal Register. See Small Business Innovation Research, GAO report 06-565, April 2005, p.5

Transparency

Under the current SBIR system, the identities of SBIR awardees are not only known, but a matter of public record. Those seeking to change the SBIR Program want this safeguard ended. They seek to eliminate SBA's requirement that SBIR companies, and any VC's that control them, be owned by individuals rather than institutions. The net effect of doing this would be to obscure exactly who, or what institutions, would derive the ultimate benefits from an SBIR award, including any resulting intellectual property. The true beneficiaries could turn out to be the same universities and large companies that already dominate federal R&D contracting. Yet the SBIR Program was created to address precisely this imbalance.

Foreign Ownership

A number of VC and biotech industry proposals for SBIR would dissolve the current requirement for SBIR companies to be controlled by U.S. citizens or permanent legal residents. Thus, U.S. taxpayers could end up financing innovations that make foreign industries more globally competitive than our own. Even defense and homeland security technologies could be diverted abroad under some of the proposals.

The Integrity of Phases 1 and 3

One key reason SBIR works, as noted, is that it funds R&D in steps. That also is at risk here.

Phase I SBIR awards, intended for very early-stage research, give agencies like NIH a competitive, rigorous, and scientific process for singling out meritorious ideas and developing them. But early-stage R&D funds like SBIR Phase I awards are quite scarce in both the private and public sectors. At NIH today, for example, only about one out of every eleven Phase I proposals is funded. The awards are in the hundreds of thousands of dollars, not the millions. Any loss of focus in NIH's Phase I, or reduction of available funds, will have significant repercussions on early-stage, life science R&D because there are so few funding alternatives.

SBIR Phase 3 is quite different. It is explicitly intended for R&D *output* -- products nearing commercialization. Phase 3 is predicated on partnerships between SBIR companies and others, such as large businesses. VC's of any size may partner with SBIR companies in Phase 3.

Phase 3 access, evidently, is not enough. What the large VC's now seek is Phase 1 access.

There are major problems with this,

• NIH and VC priorities for basic R&D differ dramatically. In the life sciences, the VC business model emphasizes innovations that have wide applicability, are close to commercialization, look likely to receive FDA approval, promise rapid triple-digit paybacks, and will be used by patients over a period of months or years. (Not incidentally, these are also the factors that most interest Wall Street.) In general, life science VC's have been very interested in "blockbuster drugs" and medical devices, but not much else. Yet much of the NIH public health and homeland security mission is devoted to other priorities – like biodefense, vaccine development, diagnostics, platform technologies, research tools, orphan disease therapies, agricultural biotechnology, and

environmental biotech. An aggressive push by large VC's into Phase 1 will -- at minimum -- create a lot of friction over such priorities. Over time, it will lead to great pressure on NIH to adapt research solicitations to VC preferences.

What VC's really want is incompatible with Phase 1. Here's a recent analysis of this
point from the biotech trade press:

"The biotech industry seems to be at a crossroads ... With the focus now on developing products that are already in clinical development ... biotech investors now seem to be more risk adverse. Their investment strategy is to focus on investing in companies with products in late stages of clinical development, which they believe will receive FDA approval." (Emphasis added)¹¹

Virtually nothing in SBIR Phase 1 fits this description. Virtually everything in Phase 3 does. And the VC and biotech communities seem to know it.

Here's a speaker from a venture capital panel at a recent Biotechnology Industry Association general meeting:

"In the late 1990s, investors were willing to back early-stage technology phases of biotechnology,' said Jim Barett, an analyst and general partner of New Enterprise Associates. 'Now the investment community is moving toward later-stage projects. That means that early-stage projects are having difficulty raising money in this environment of risk discounting.'" 12

This raises a very interesting question: why do the big VC's want in to Phase 1?

The most logical answer is that they want access to the increasingly large NIH SBIR awards¹³ -- and that they intend to bend the entire SBIR Program at NIH to their preference for later-stage research.

SBTC believes that Congress should not be a party to any such unraveling of the SBIR Program.

Alternative NIH Funding Channels Available to Larger Companies

NIH has a variety of grant and contract programs that draw on the 971/2% of its extramural research funding that is <u>not</u> allocated to SBIR. And over 40% of NIH funding now goes to applied, as opposed to basic, research. ¹⁴ These programs do not require an applicant company to <u>be small</u>. Among them:

^{11 &}quot;Wall Street Biobeat" John Wong, Ph.D., Genetic Engineering News, March 1, 2005, p. 60.

^{12 &}quot;Investors: Show us the Drugs," Business Gazette, June 24, 2005

¹³ This is especially remarkable in view of the \$53.6 billion cash hoard of funds held by venture capital companies in 2005 but not invested in venture projects. See "Overhang of Venture Capital Funds at \$53.6 Billion" Dow Jones / VentureOne Press Release, March 24, 2005. www.ventureone.com/ii/VI-FundsOverhangSurvey2005.pdf Note, too, that over half of NIH's awards exceed federal guidelines, a major enticement to the VC's. See footnote 10.

¹⁴ "NIH at the Crossroads: Myths, Realities and Strategies for the Future," Elias A. Zerhouni, M.D., Director, National Institutes of Health, May 22, 2006 presentation, NIAID Council., p. 5

- Exploratory/Developmental Research Grants (R21). These support pilot-scale studies for potentially ground-breaking ideas, methods, and systems that meet the following criteria: they lack sufficient preliminary data, their successful demonstration would have a major impact on biomedical research, and they fall within the areas supported by the awarding institute. A second stage of the R21 grants, R33 grants, is parallel to SBIR Phase 2. These grants are rising rapidly. At the National Cancer Institute, which is the largest of the National Institutes of Health, R21's have risen from 34 grants, valued at \$7.6 million in 1995 to 425 grants, valued at \$77.9 million in 2004. Meanwhile, R33's, which began in 1999 with 6 grants valued at \$2 million, have risen to 96 grants, valued at \$42.9 million in 2004.15
- Individual Basic Research Grants (R01) are awarded to eligible institutions/organizations on behalf of a principal investigator to support a discrete hypothesis-driven research project related to the investigator's area of interest and competence.
- Program Project Grants (P01) are more complex in scope and budget than the individual basic research (R01) grant. While R01s are awarded to support the work of one principal investigator who, with supporting staff, is addressing a scientific problem, program project grants are available to a group of several investigators with differing areas of expertise who wish to collaborate in research by pooling their talents and resources. Program project grants represent synergistic research programs that are designed to achieve results not attainable by investigators working independently.
- Small Research Grants (R03) support small research projects that can be carried out in a short period of time with limited resources for projects such as pilot studies; secondary analysis of existing data; small, self-contained research projects; and development of research methodology. R03 grants often are used as a stepping stone to a new investigator's first R01 grant.

A good example of the parallelism that is developing between the SBIR awards and the "Exploratory / Developmental Research Awards" (R21) awards can be seen in two recent NIH solicitations bearing the same title: "Development of Advanced Genomic Characterization Technologies" - one an SBIR solicitation and one an "R21". 16 The solicitations are nearly identical.

SBTC urges the venture capital and biotechnology communities to work with NIH in developing these promising channels of research funding that do not impinge on the SBIR Program.

SBIR Awardee Preferences

Proponents of large VC control of SBIR companies have argued that they were responding to pleas from the SBIR companies themselves. Since we at SBTC had heard only criticism of the proposal from our member companies, we wondered about that. So we took a survey.

NCI Fact Book 2004, National Cancer Institute, 2005, P. E-3
 The R21 solicitation will be found at: http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-07-021.html. The SBIR solicitation will be found at: http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-07-029.html

We contacted every NIH SBIR Phase 1 and Phase 2 awardee from 2003 and 2004. We sent them a link to a position paper favoring the change that was posted on the Biotechnology Industry Association (BIO) website, and a link to a position paper opposing the change that was posted on our website. We asked the companies to read the two position papers and then vote on whether to support or oppose the change.

Just over 13% of the companies replied – not a bad response rate in view of the time required to read the two position papers.

Of these, 90% opposed the VC eligibility change advocated by BIO.

This result speaks for itself: The companies most affected by the proposed change, who theoretically stand to gain from it, are overwhelmingly opposed to it.

And that's not all. At a large conference on SBIR Phase 2, speakers advocated both sides of the issue, after which a written ballot was taken of attendees. The vote count was 1 in favor (the speaker in favor, presumably) and 149 opposed.

In my own state, the respected New England Innovation Alliance has strongly opposed these changes. 17

SBTC's 19-member Board of Directors voted *unanimously* to oppose the large VC position in 2003. From then, through today, *not one single SBTC member company* has voiced an objection to our position. In fact, we have attracted a number of small biotech companies to SBTC membership *because of* our opposition to the VC position.

Harvesting Innovations From All Regions of the Country

Allowing large VC's to control SBIR companies also would be likely to further concentrate SBIR awards around Boston and the San Francisco Bay area, where many VC's are headquartered and where they make 58% of their investments. While I myself come from the Boston area, it's apparent to me that Congress meant for the SBIR Program to attract the widest possible swath of applicants, from all across the country. Indeed, that's why Congress created the Federal and State Technology Partnership (FAST) Program and the SBIR Rural Outreach (RO) Program.

But today ten states account for 85% of all VC investments. Despite the 750-850 venture capital deals done annually in the U.S., at least a dozen states received two or fewer of them annually for most of the past ten years. That list includes Maine, Montana, South Dakota, Louisiana, Wyoming, Iowa and Arkansas. Likewise, none of the 100 largest VC's were located in thirty-one states. And only two percent of venture capital goes to seed and early stage investment -- the type SBIR companies need most.

At the Maryland Technology Development Center in Rockville, MD, a county-operated facility that houses perhaps the largest concentration of small biotech firms in the mid-Atlantic region, not a single biotech company has raised a first round of venture capital during the past five years -- but most have successfully competed for SBIR Phase 1 and 2 contract awards. Tilting the SBIR

¹⁷ Accessible at www.nsba.biz/docs/neia_letter.pdf

¹⁸ See Money Tree Venture Capital Profile for the United States, www.ventureeconomics.com/vec/stats/2006q1/nation_us1_html#state and PriceWaterhouse Coopers Money Tree Report, www.pwcmoneytree.com/moneytree/nav.isp*page=historical

playing field against companies like these – who have not the slightest prospect of VC funding – will guarantee that many of them will disappear. When they go, their potential life science innovations will likely go with them.

Avoiding Potentially Dangerous Legal Precedents

Contravening SBA's affiliation rule, and SBIR's statutory limit on the size of businesses that can access the Program, carries with it significant legal risks.

Large corporations like the Bank of America and Intel already operate their own venture capital companies. Not only would such "corporate" VC's enter the SBIR Program if SBA's affiliation rules are changed, but the incentive for other corporations to *create* more such VC's would dramatically increase. Corporations like Boeing, Genetech, Lockheed Martin, Microsoft, and the large pharmaceutical firms could be expected to form venture capital companies for this explicit purpose. Soon small companies competing for SBIR awards throughout the government would find themselves fighting with Fortune 500 corporations for the small SBIR share (2½%) of federal R&D dollars.

It would be unlikely to end there, either. Once such large corporations have broken through the legal framework that has kept them out of the SBIR Program, there would be no equitable argument for keeping universities and other large research institutions from participating in the SBIR Program via their own VC's.

Stepping a bit further back, if SBA waives its affiliation rules in this situation – for the first time in the fifty-three year history of the agency and the Small Business Act – it would open up every other small business program in the nation to challenge.

If large companies can force their way into the SBIR Program, why should they be kept out of the SBA's other federal procurement programs, its 7(a) lending program, its Small Business Investment Company program, its surety bond guarantees? Why should SBA's Office of Advocacy continue to distinguish between large and small companies in its efforts to reduce the federal regulatory burden?

The implications of this proposed rule thus transcend the SBIR Program itself, federal R&D contracting, or even overall purchasing practices by the federal government.

The real nub of the issue is whether a large business can take over a small business and still get the federal government to call it "small." If Microsoft controls and funds Sam's Computer Repair, is Sam's a "small business" or a part of a large business?

Sooner or later, the public will come to see it in these terms.

At heart, then, this is simply a classic dispute between small business and big business.

What a few large companies seek here is nothing less than a breach of the single most fundamental principle of federal small business law: that a small business is one which is "independently owned and operated". That was the language used in the Small Business Act over half a century ago, and it is the foundation upon which dozens of subsequent laws, and hundreds of subsequent regulations, are built.

Eviscerating this principle to placate a handful of companies that are trying to tap a pool of funds at one agency cannot be the vision that Congress and the American people have for the nation's canon of small business laws and protections.

SBTC strongly urges Congress to be vigilant in discerning the long-term consequences of any actions in this legal area.

Need For Change Not Established

Perhaps some of these concerns could be set aside if the need for this change were more clearly established. That hasn't happened. On the contrary, key assertions made by the proponents of the change have been *disproven* in a recent GAO report. ¹⁹

- Proponents say the number of SBIR awardees at the National Institutes of Health
 (NIH) with VC backing is dropping. GAO says the number is up more than 50% since
 SBA clarified its long-standing rules on VC's in 2002. Phase 2 awards are up over 70%.
- Proponents say the quality of SBIR research at NIH is dropping. GAO says research
 quality is rising.
- Proponents say VC-backed companies are getting fewer dollars from SBIR awards at NIH. GAO says VC-backed firms now account for more than \$1 out of every \$5 that NIH awards. That's up more than 50% over three years.
- Proponents strongly imply that the SBIR Program at NIH isn't working. Numerous studies, cited earlier, by GAO, the National Academy of Sciences, and other independent organizations say the Program is successful.

And one more thing.

Proponents say that NIH endorses the changes they seek. In a letter to SBA Administrator Hector Barreto dated 28 June 2005, NIH Director Elias Zerhouni stated that NIH wished to award SBIR funds only when "applicable small business affiliation standards are satisfied." In a second letter, to Anu K. Mittal of GAO (who directed the above study), dated 16 June 2006, NIH Deputy Director of Extramural Research Norka Ruiz Bravo repeated NIH's concern that "applicable small business affiliation standards are satisfied" in any changes affecting the NIH SBIR Program. The letter then reiterated that:

"NIH is committed to insuring that only small business concerns receive SBIR awards." (Emphases in originals.)

For these reasons, SBTC asks Congress to maintain the prohibition in the SBIR Program against venture capital company control of SBIR contract awardees when the VC's involved do not meet the current legal definition of a small business.

¹⁹ Small Business Innovation Research, GAO Report 06-565, April 2006

Senator Thune. Madam Chair? Chair Snowe. Yes, Senator Thune.

Senator THUNE. I have a statement I could submit for the record. Chair SNOWE. Absolutely. Without objection, so ordered. Would you care to make any comments?

Senator Thune. No. I just thank you for holding the hearing as we lead up to the reauthorization, and I thank our panel for their excellent testimony.

Chair Snowe. We appreciate it. Thank you.

[The prepared statement of Senator John Thune follows:]

PREPARED STATEMENT BY SENATOR JOHN THUNE

Madam Chair, other members of the Committee, I would like to thank you for holding this hearing today in anticipation of the upcoming SBA reauthorization. It is important that, as a Committee, we provide oversight to the many programs SBA uses to help create and strengthen small businesses across our country.

The programs we are focusing on today are important to our small businesses. Although small businesses employ half of the private workforce and make up 99.7 percent of all employers, they would not get their share of government contract work without help. The SBA works to ensure that Federal contracts are not only going to the big guys, but the little guys as well. We need to make sure that small business contracting regulations and systems are up to date and effective, but not overly burdensome. There will always be a handful of bad actors who try to game the system, so we need to be vigilant to make sure these contracts are actually going to the small businesses as intended.

We are also focusing on the Small Business Innovation Research Program (SBIR) and its effectiveness. I am glad to see that we have a witness from my neighboring State of Wyoming here today. Mr. Watson, thank you for coming to testify today about your experiences with this program. Unfortunately, when there are research and development dollars that need to be invested, rural America is not always the first place that comes to mind. Although I think people that live outside of the city limits are often some of the most innovative and entrepreneurial folks we have in this country, venture capital dollars and R&D resources rarely make their way out there.

The SBIR program, which reserves a specific percentage of Federal R&D funds for small businesses, has helped reverse that trend somewhat. It is my hope that we can come to a consensus on how to best fashion the SBIR program so that it doesn't create a chilling effect in the biotech industry. And make sure it does not further shut out rural entrepreneurs from the already scarce R&D dollars out there.

Finally, I would like to thank all the witnesses for their willingness to testify before the Committee before we begin the important work of reauthorizing the programs of the SBA. Your input, along with that of all of our constituents that we hear from day in and day out, gives us the information we need to make these policy decisions. Decisions that will hopefully help strengthen America's small businesses.

Chair Snowe. Mr. Bigger, welcome.

STATEMENT OF THOMAS J. BIGGER, PRESIDENT AND CHIEF EXECUTIVE OFFICER, PARATEK PHARMACEUTICALS

Mr. BIGGER. Thank you. Chairwoman Snowe, Ranking Member Kerry, and members of the Small Business Committee, thank you for providing me with the opportunity today to testify before you. My name is Thomas Bigger, and I am the president and chief executive officer of Paratek Pharmaceuticals. Paratek is a privately held, venture-backed biopharmaceutical company located in Boston, Massachusetts. Paratek was founded in 1996 by Dr. Stuart Levy, a professor at Tufts University School of Medicine, and Dr. Walter Gilbert, a Nobel Prize-winning professor emeritus at Harvard University.

Paratek's primary mission is to develop novel antibiotic and antiinfective agents that overcome the critical worldwide problem of bacterial resistance. Today, however, I am here to testify on behalf of the Biotechnology Industry Organization, BIO, an organization representing more than 1,000 biotechnology companies like myself, academic institutions, State biotechnology centers, and related organizations in 50 U.S. States and 31 other nations. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products.

As a representative of one of the most innovative, high-growth sectors of our Nation's economy, one in which the United States maintains a global leadership position, my testimony will focus on the urgent need for reforms in the current eligibility rules of the Small Business Innovation Research (SBIR) program. Senator Bond has introduced legislation, Senate bill 1263, the Save America's Biotechnology Innovation Research Act, which would make the necessary reforms to the SBIR program. These reforms are essential in providing early-stage biotechnology companies with the opportunity to compete for, as they did for over two decades, and participate again in the SBIR program. Without reform, we could seriously jeopardize America's innovation leadership and competitiveness in the global biotech marketplace.

Small biotech companies often rely on SBIR Phase I and II grants to fund research in areas that most private investors or venture capitalists will not fund because they consider these areas to be either too early-stage to fund, too risky from a market opportunity standpoint, or simply lacking in sufficient commercial returns.

For the first 21 years of the program, the SBA interpreted individuals to include individual entities or investment groups, as long as they are majority-owned by Americans. However, in 2001 and 2003, SBA changed the eligibility rules which denies majority venture-backed companies from participating in the SBIR program.

Paratek has experienced firsthand the detrimental effects of this rules change. In 2003, due to the changes in the SBIR eligibility rules, we had to turn down a Phase II grant and shut down a key antibiotic therapy research program, where ultimately we had to lay off 10 employees. This program was originally started with Phase I SBIR grant funding in 2001, and the NIH had urged us to accept the grant despite the eligibility changes in order to continue this valuable research.

Some have raised the question that biotechnology companies that are majority owned by venture capital companies are somehow no longer small businesses. Nothing could be further from the truth. Paratek, with 66 employees, is a small business, regardless of whether we get funding from a bank, from a venture capitalist, or from individuals. What separates biotechnology companies from less capital-intensive industries is the sheer amount of money, the length of time necessary for development, and the required FDA approvals to bring a product to market. As such, private investment is not an option. It is an absolute necessity.

It is also critical to make it clear that venture capitalists invest in biotechnology companies and programs because they hope to realize a return on their investments. These managers invest in a wide range of companies so as to diversify their risk. Their job is managing money, risk, and return, not running a business, and certainly not running a business to obtain SBIR grants.

As an example, at Paratek the management and individual investors own approximately 45 percent of the interest in the company. We have 15 different private investment groups who own at most 5 percent each. Only one of these firms out of the 15 has a board seat, and we can safely say that Paratek's management controls the day-to-day management and direction of the science.

Some have also argued that the recent changes in the SBIR eligibility rules are consistent with the goals of the SBIR program. The congressional record indicates otherwise. The SBIR statute and its legislative record demonstrate that Congress intended to encourage venture financing of SBIR awardees.

Paratek embodies what Congress originally intended with respect to the SBIR program. We employ highly educated and skilled scientists that would like to make contribution to the treatment of diseases in areas where there are significant unmet needs, but where the commercial value is too low to justify private investment at early stages of research. We believe that we have the technology that can be put to use in areas such as the treatment of malaria, filarial disease, anthrax, spinal muscular atrophy—which is a severe disease that affects a small population of children—and other orphan and niche diseases. However, without SBIR funding to advance our research in these areas, it is unlikely that we will be able to pursue potentially compelling treatments. As a result, much of this innovative technology will sit on the shelf.

So, really, the time is now for this committee to consider and support SBIR eligibility reform. Senator Bond has introduced Senate bill 1263. We urge all the members of this committee to support Senate bill 1263 and to include it as part of the SBA reauthorization act this year. SBIR reform is critical now in order that U.S. biotechnology companies can continue to innovate and remain competitive in the global marketplace.

Thank you.

[The prepared statement of Mr. Bigger follows:]





Hearing Testimony Thomas Bigger President and CEO Paratek Pharmaceuticals

On Behalf Of The Biotechnology Industry Organization

Before the Small Business Committee United States Senate

"Strengthening Participation of Small Businesses in Federal Contracting and Innovation Research Programs"

July 12, 2006

Chairwoman Snowe, Ranking Member Kerry and the Members of the Small Business Committee:

Thank you for providing the opportunity to testify before you today on strengthening the participation of small businesses in the federal innovation research programs.

My name is Thomas Bigger. I am the President and Chief Executive Officer of Paratek Pharmaceuticals. Paratek is a privately-held, private investment company-backed biopharmaceutical company located in Boston, Massachusetts. We are considered an early-stage company having only one program in the clinical stage, while the majority of our programs are in pre-clinical development.

Paratek is engaged in the discovery and commercialization of new therapeutics that treat life threatening infectious and other serious diseases. Paratek was founded in 1996 by Dr. Stuart B. Levy, Professor at Tufts University School of Medicine, and by Dr. Walter Gilbert, a Nobel Prize winning Professor Emeritus at Harvard University.

Paratek's primary mission is to develop novel antibiotic and anti-infective agents that overcome the critical worldwide problem of bacterial resistance through the application of our two proprietary technology platforms. Paratek utilizes these platforms, Tet and MAR, to develop multiple products to combat, cure, and prevent infections, such as serious and resistant bacterial infections, and other serious diseases, such as pseudomonal infections, malaria and anthrax, as well as inflammatory diseases, such as asthma, arthritis, multiple sclerosis, and stroke.

Today, I am here to testify on behalf of the Biotechnology Industry Organization (BIO), an organization representing more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations in 50 U.S. states and 31 other nations. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. The majority of BIO member companies are small, early stage research and development oriented companies pursuing innovations that have the potential to improve human health, expand our food supply, and provide new sources of energy.

As a representative of one of the most innovative high growth sectors of our nation's economy -one in which the Unites States maintains a global leadership position -- my testimony will focus
on the urgent need for reforms in the current eligibility rules of the Small Business Innovation
Research (SBIR) program. Senator Bond has introduced legislation, S.1263, the Save America's
Biotechnology Innovation Research Act (SABIR Act), which would make the necessary reforms
to the SBIR program. These reforms are essential in providing the most innovative early stage
biotechnology companies with the opportunity to compete for, as they did for over two decades,
and participate again in the SBIR program. Without reform, we could seriously jeopardize
America's innovation leadership and competitiveness in the global biotech market place.

Changes in SBIR Eligibility Rules - Cost to U.S. Biotech Innovation:

Early-stage biotech companies rely on risk capital and, increasingly, federal grant sources to fund research and development activities. Small biotech companies often rely on SBIR Phase I and II grants to fund research and/or development in areas that most private investors or venture capitalists won't fund because they consider these areas to be either too early-stage to fund, too risky from a market opportunity standpoint, or simply lacking in sufficient commercial returns.

To qualify for the SBIR grant, a small business applicant must meet certain eligibility requirements. The size and ownership requirements — or "size standard" — limit eligibility to those companies that are: 1) 51% owned and controlled by one or more *individuals* who are U.S. citizens or permanent residents and 2) have no more than 500 employees, including any affiliates.

For the first 21 years of the program, the Small Business Administration (SBA) interpreted individuals to include individual entities or investment groups, as long as they were majority-owned by Americans. However, on January 10, 2001, the SBA Office of Hearings and Appeals ruled in CBR Laboratories, Inc. that the definition of "individuals" no longer included venture capital firms or other investment groups, including funds established by patient groups to support research. Instead they chose to follow a very strict, unorthodox interpretation not followed by other federal agencies that the legal term "individuals" referred only to actual individual human beings, not individual investor groups. This new interpretation of "individuals" resulted in the denial of an SBIR grant in 2003 to Cognetix, a Utah biotech company, because the company was backed by private investment firms in excess of 50% in the aggregate. Many biotech companies have since been denied the opportunity to compete for the SBIR grants and as a result, their work on life-saving and life-enhancing technology is being indefinitely postponed.

Paratek has experienced first hand the detrimental effects of no longer being able to compete for and participate in the SBIR program. In 2003, specifically due to the changes in the SBIR eligibility rules, we had to turn down a Phase II grant and shut down a key antibiotic therapy research program, where ultimately, we had to off 10 employees. This program was originally started with Phase I SBIR grant funding in 2001, and the NIH had urged us to accept the grant despite the eligibility changes in order to continue this valuable research. Because we strongly believed in our technology, we pursued other sources of funding, such as from philanthropic

foundations. However, we were unable to find alternative funding until 2 years later, ultimately delaying patient access to the novel therapies that much longer.

The majority of BIO's members who are private companies have also faced similar fate due to the arbitrary changes in the SBIR eligibility rules in 2001 and 2003. For instance, a privately-held, venture-backed, biopharmaceutical company located in St. Louis, Missouri, raised their first or Series A round of financing in 2001. Because of the reinterpretation in the rules, they were unable to participate in the SBIR program and as a result, had to cancel the development of their bio-defense vaccine program. This company's technology, with additional development, could have delivered massive quantities of vaccines against anthrax, cholera, and other diseases as part of America's biodefense and pandemic preparedness efforts.

While there are very few other government grant programs, such as NIH's Cooperative Agreement Program (U-01), for which companies like Paratek could submit applications, these programs are not designed for early stage, innovative research. In majority of the cases, funding requests for certain diseases are only available through the SBIR program. Even if one could pursue a U-01 grant, the U-01 program typically requires the submission of a substantial body of data and the demonstration that the technology is far more advanced than the proof of concept stage – meaning that significant funding would already have been required for the programs to get it to the point of being competitive for these particular grants. Moreover, truly small biotech companies like Paratek are often squeezed as we may be competing with large international pharmaceutical companies to secure these other types of grants. The SBIR program fills the funding gap that allows small companies like Paratek to continue to innovate and move early stage research forward to the point where we can compete for U-01 and other grants or sources of funding.

BIO member company concerns regarding the impact of current eligibility limitations on biotech innovation are shared by Dr. Zerhouni from the National Institutes of Health (NIH). Dr. Zerhouni, in his letter dated June 15, 2005, strongly urged the SBA to revise its SBIR rules to remedy current rules that "unduly restrict the ability of NIH to fund small companies that receive venture capital investment. [Since] as a result [of the changes in rules], NIH must turn away many deserving applicants and the goals of the SBIR program are being undermined." NIH raised their concerns again in June 16, 2006, in a letter to the GAO regarding their study on the SBIR program. In its letter, NIH reiterated its belief that "the impact of current eligibility rules presents a significant roadblock in our technology development pipeline and ultimately in the speed in which important products to improve health are brought to market."

Reality Check: Role of Private Investors and Venture Capital in Biotech Companies

Some have raised the question that biotech companies that are majority owned by private investors or venture capital companies are somehow no longer small businesses. Nothing could be further from the truth. Paratek, with 66 employees, is a small business regardless of whether we get funding from a bank, from venture capitalists or from individuals. What separates biotechnology companies from less capital-intensive industries is the sheer amount of money, the length of time necessary for development, and the required Food and Drug Administration approvals to bring a product to market. The development of a new biotech drug or therapy requires years of research and testing, and hundreds of millions of dollars and often takes a decade or more. As such, private investment is not an option, it is a necessity.

It is also critical to make the distinction that early stage investment firms and venture capitalists invest in biotechnology companies and programs because they hope to realize a return on their

investments, and not because they want to run or control the biotech company. In fact, most venture capital companies are very small organizations, usually operated by 4 to 6 managers. These managers invest in a wide range of companies so as to diversify their risk. Their job is managing money, risk and return; not running a business, and certainly not running a business to obtain SBIR grants. Moreover, just because a company is able to attract private funding does not mean that private investment firms will fund every program. As stated earlier, private investors are often unwilling to fund early stage projects or those with limited potential for commercial return no matter how compelling the therapeutic need.

To further reduce risk, most private investment firms invest as members of a group with other firms. As such, private investment firms typically acquire only minority interests in, and do not control their portfolio companies. In the biotech industry, this tends to be between a 5 to 20 percent interest in any one company. Private investment firms do not have the time, staff, or the desire to engage in the day-to-day operations of their portfolio companies.

As an example, at Paratek, the management and individual investors own approximately 45% of the interest in the company. We have 15 different private investment groups who own at most 5% each. Only one of these firms out of the fifteen has a board seat, and we can safely say that Paratek's management controls the day to day management and direction of the science and not the investors.

Current SBA Regulation Lacks Congressional Mandate

Some have also argued that the recent changes in the SBIR eligibility rules are consistent with the goals of the SBIR program. The Congressional record indicates otherwise. The SBIR statute and its legislative record demonstrate that Congress intended to encourage venture financing of SBIR awardees. In fact, the SBIR statute lists a company's ability to attract private investment and to commercialize its product as a factor to be favorably considered by the contracting agencies in awarding SBIR grants. Indeed, some would argue that the companies that are able to attract private investment are likely to be the ones that have the talent, experience and infrastructure to be best able to identify and make the most of promising, innovative technologies.

The record shows that one of Congress' most important goals was to assist small business concerns as a way to lead the technological advancements in the United States. This point is well demonstrated in the House Small Business Committee report, which states that the legislation was "aimed at stimulating innovation in general and at stimulating the technologically and innovatively oriented small business sector." H. Rept. 97-349, 97th Congr., 1st Sess. 1981 at page 17. Moreover, Congress deliberately sought to promote those businesses that had attracted private sector backing and showed no inclination whatsoever to exclude venture-backed small firms from the program.

In fact, the SBIR program was originally intended for agencies to give preference to companies that have received Phase I grants and have attracted private sector funding to pursue commercialization of their products. The Senate Small Business Committee explained that "[t]his special consideration serves as a built-in incentive for participants in the program to seek ways to build upon the federal research, thus fulfilling one of the bill's primary objectives." S. Rept. 97-194, 97th Cong., 1st Sess., 1981 at page 2. Thus, the SBIR program was specifically meant to "facilitate" the ability of participating firms to attract venture capital, not to prohibit it, as SBA's current regulatory interpretation does by requiring 51% ownership by "natural persons". Thus, the SBA's interpretation of the eligibility rules not only greatly hinders the best

innovators from competing but also seems to defy Congress' intent behind the SBIR program itself.

Paratek embodies Congress' original intent with respect to the SBIR program. We employ highly educated and skilled scientists and other associates. Our novel scientific agents have been validated in Phase I grants and we were urgently in need of the SBIR grant for further validation in a Phase II grant. Although our science showed great promise, in 2003, many private investors were reluctant to fund the programs until we could demonstrate additional proof of concept. As Congress intended, SBIR grants are essential in supporting this early stage research, which further validates and often proves persuasive for additional investment by private investors.

Moreover, companies like Paratek would like to make contributions to the treatment of disease in areas where there are significant unmet needs but where the commercial value is too low to justify private investment at the early stages of research. We believe that we have the technology that can be put to use in areas such as the treatment of malaria, filariasis, spinal muscular atrophy – a severe disease that affects a small population, and other orphan and niche diseases. However, without SBIR funding to advance our research in these areas to the point where we can get other funding, such as from foundations or even U-01 government grants, it is unlikely that we will be able to pursue potentially compelling treatments. As a result, much of this innovative technology will sit on the shelf.

Urgently Need SBIR Eligibility Reform - Support S.1263

The time is now for this Committee to consider and support SBIR eligibility reform. Senator Bond has introduced S.1263, the SABIR Act in 2005. Many of the members of this Committee are co-sponsors. This legislation provides small but majority venture backed companies the opportunity to compete for the SBIR grants. This very important legislation will reverse the misguided SBA interpretation regarding the SBIR rules and return its eligibility standards to where they had been for 21 years prior to 2003. We urge all the Members of this Committee to support S.1263 and to include S.1263 as part of the SBA Reauthorization Act this year. SBIR reform is critical now in order that U.S. biotechnology companies can continue to innovate and remain competitive in the global market place.

Chair SNOWE. Thank you, Mr. Bigger, and I want to thank all the panelists here today. Obviously, we are addressing an array of issues as we proceed to the reauthorization of SBA, and as well, we hopefully will be able to resolve some of the issues here today I think reflected in your testimonies as well and your varying perspectives because these are, obviously, critical programs in the ab-

sence of support for small businesses.

Mr. Thorson, let me just begin with you on the question of contract bundling. Obviously, we have heard your perspective here today as inspector general. There was a report that was completed, you know, prior to your taking this position back in March on the questions, and what you are speaking here today. And last time we received testimony from the Office of Government Contracting and Business Development contradicting some of the issues. And I would like to have you explain to us here today, because I think it is important. The contract bundling has been a vexing challenge for the small business community in America. It is problematic to me on a number of fronts, not the least of which, of course, is that the SBA has not reviewed these contracts, in spite of what I think has been said here in this testimony, which they claim that they have reviewed the preponderance of contracts before they were awarded. But I think that that is the question as to whether or not they were actually reviewed at that process or submitted and gone to OMB and already awarded and, therefore, never reviewed in terms of their compliance with the bundling obligation.

Secondly, the President did say, you know, 18 months ago, that there is a huge problem with these contracts and the massive requirements. And it seems to me that agencies have really moved in a diametrically opposed position. They have now decided to avoid the requirements of contract bundling by claiming they are existing modifications or they are indefinite—I guess what you have described as indefinite delivery contracts and, therefore, do not qualify as new contracts, as a way of avoiding the whole con-

tract bundling question.

Could you speak to those issues here today? And, also, I would like to have you tell us what you think we ought to be doing in the reauthorization, because I do think we should have some severe penalties in law for those companies, those large companies, you know, that sort of masquerade as small companies, you know, using small businesses as fronts for getting access to these Federal contracts. And we have already had one company, Insight, which was a multinational, publicly traded corporation for misrepresenting itself as a small business for Federal contracts, and it had a workforce of 4,000 employees and annual revenue of \$3.3 billion. And its predecessor company had been misleading the Federal Government as to their small business status for over 10 years.

How does this come about? And what can we do to resolve these

questions once and for all?

Mr. Thorson. On the bundling issue, first of all, we will take kind of a simplistic approach to a rather complex issue, and that is, we know that there were in one case over 200 issues reported to OMB and about 20 to SBA. Now, the OMB reports are after the fact, as you pointed out, and in SBA you are reporting it before-

hand because you are asking for an analysis and, in a sense, permission.

At best, we felt that SBA ought to find out why there was a discrepancy. Clearly, there is something wrong here. The very best case is people have made a mistake in reporting the bundling, and I think in their statement they refer to the fact that we do not know this was bundling. Probably true. But find out. Why not find out?

And if the IG can go find out and if the OIG can go find out in a very short period of time to see what was reported to OMB, our position was that SBA should really do the same.

If it is a matter of an error, then we believe that some education is required to clear up this process, because there are reports of

bundling that are incorrect.

If it is not an error and those truly were bundled contracts that were reported to OMB, then we have another problem that is probably even bigger, and that is, the motivation as to why they did not come to SBA first. And I think the obvious reason there is they did not want to have to go through that particular process. We do not know that, but it is a good guess.

So, again, going back, the simplistic view is our position is that SBA needs to find out where this discrepancy arose from and why

it is there and what they can do about it.

Chair SNOWE. Well, you know, do these companies have to recertify each time they are submitting a bid? I mean, you know, if they are going to try to bypass the whole process in one way or the other, then obviously we have got a loophole and we are going to have to figure that one out. And the first question, Is there a requirement that they would have to recertify every time they submit a bid?

Mr. THORSON. Well, the final ruling that SBA has issued is regarding companies that are sold to large companies, and at that point, they must recertify.

Our position is we would like to see annual recertification. We think that exerts the best control. I do not believe SBA is 100 per-

cent behind that particular viewpoint.

Chair SNOWE. Well, I guess what you are saying is essentially SBA is not being a strong advocate and certainly not being aggressive on this question, and that is why we have massive inroads into the current—you know, by large companies or otherwise that have really eroded small businesses' ability to even access these contracts.

Mr. Thorson. That is right, and we do believe that there is better control over this by enforcing some form of recertification. Our position is 1 year because that is the tightest. If companies are required to do that, then it makes it very difficult for them to try and slip under the wire on some of these other things as other contracts come up.

Right now I believe the issue is for 5 years, and so for 5 years, assuming for sake of argument the first contract causes you to move into the large business category, for the next several years you are going to be able to continue to bid. And I think that is the point that was being made by our position on annual recertification.

cation.

Chair SNOWE. And why has the rule proposed by SBA language for 3 years? You know, what are the barriers there? Agencies? Other agencies?

Mr. THORSON. The one that we referred to that has been 3 years before?

Chair Snowe. Yes.

Mr. Thorson. I really cannot answer that. That question is one that we continue to ask.

Chair Snowe. To which you have received no answer?

Mr. THORSON. Yes. Chair SNOWE. Okay. Also, on suspending or debarring companies from Government contracts based on violation of the SBA procurement size regulation, you have asked Congress to give SBA that authority. Frankly, I think that this is a direction that we obviously ought to move and incorporate some of these strong penalties within law. Yes?

Mr. Thorson. I am sorry. I couldn't quite hear the question.

Chair Snowe. Oh, I am sorry. It was concerning—you asked Congress to give SBA the authority to prosecute, to debar companies who engage in fraudulent activities and disguising, you know, their

status as a small business company.

Mr. THORSON. Right. On the debarment issue, first of all, I think there is a general reluctance to want to go down that road, anyway, on behalf of the agency. But the issue really became one of, well, do we really have the authority at SBA? Or is the procuring agency the one that needs to pursue that? And then each looks at the other to follow that path and nothing gets accomplished.

What we are looking for here is a clearance so that SBA truly has the very clear understanding that they have that authority and

that they can pursue it when it is warranted.

Chair SNOWE. But I gather on some of the—I mean, I think in terms of the promulgation of that rule, that some of the major agencies, such as GSA and Defense Department, had objected to it.

Mr. THORSON. Yes. Actually, a lot of the definitions and the regulations and the issues as we read them, really do create an issue

of unenforceability.

If you are looking for a way not to pursue a difficult path—which certainly these are difficult—they are confrontational. They are sort of against the general trend of, "We are supporting the small business here." They do not necessarily want to get into that role. It is easy to duck it because of the fact that the regulations really are such that it is difficult to enforce.

Chair Snowe. Yes, and I think that we really do have to strengthen the enforcement one way or the other. I think as your office indicated and your testimony, over 80 percent of these bundled contracts have not been reviewed. I think that is a startling statement. Now, they do not try to, you know, disagree with that, but I think the evidence is in the numbers. And the fact is it illustrates that we have got a serious problem and that small business being denied access to Federal contracts, you know, in many ways and in many forms.

Mr. Sims, would you care to address this question at all?

Mr. SIMS. I was just going to say I support the notion of recertifying annually. And a parallel in the minority business side, we do certification for corporate America, and we have come across these new constructs of businesses where a major corporation will buy 49 percent of a minority-owned business; therefore, they get 100 percent of every contract they are able to bring in and 49 percent that

the minority business brings in.

We have sat down and put a task force together to look at the criteria to ensure that these new businesses meet not only the content of the law but the spirit of the law. And the notion of having someone come as a front—it is nothing more, nothing less—jeopardizes and threatens the integrity of the entire program. So we are looking at how do we go about ensuring for minority businesses that they remain in charge and remain in control of their own destiny. And I think that that is something that may be taken under advisement and consideration.

Chair SNOWE. I appreciate that, because I think that is a very

critical point as well.

Dr. Wessner, you offered some very interesting testimony and presentation on the value of the SBIR program, and obviously that is at the heart of the question here today, particularly the role that venture capital firms should play or could play in the SBIR program. And you illustrated the point in your presentation that large U.S. venture capital markets are not focused on early-stage firms. I would like to have each of you address this, because we are trying to figure out where is the middle ground here, making sure that we have venture capital firms that can play a role, but at the same time don't dwarf, you know, the smaller firms, the individuals, or the States that do not have large venture capital firms so that it inhibits their ability to participate in this program.

Mr. Bigger, I know you represent pharmaceuticals, and, again, pharmaceuticals generally—it is a long-term investment, but generally it is in the later stages as Dr. Wessner indicated in his statement about the fact that large venture capital firms do not focus

on early-stage development.

Is it possible to create sort of a post-Phase II, you know, that concentrates perhaps more in-depth to the commercialization, the potential commercialization of a product and whether or not it would be able to be brought into market? And it would address your question, Mr. Bigger, without, I think, intruding on the value of the program and the essence of it originally and the way in which it was designed.

Dr. Wessner, do you think that is possible? I mean, do you think

that that would work?

Dr. Wessner. Thank you, Senator.

Chair SNOWE. If you would answer that question, then we will

defer to Senator Kerry because he has to go to the floor.

Dr. Wessner. Certainly. One qualification first is that we are addressing here today the concept, its virtues, and how the markets actually work. I am sensitive to Senator Kerry's observation that our work is grounded in previous analysis that we have before us, but the report itself is not out.

To answer your question, I can, therefore, only give a partial answer. The Academy is not yet prepared to make a recommendation, but there are two key points. One is that we have with the agencies, as a result of the interest that they have brought to this pro-

gram, you have at NSF, for example, a Phase IIB program that brings in additional funds and a Phase IIB Plus, we like to joke, not to be confused with Phase III, of course.

[Laughter.]

Dr. WESSNER. But it does seem to bring additional funds forward, and for the Phase IIB and the Plus, they are required to provide matching private sector funds. So that, I would simply suggest

from our observation, shows one avenue forward.

But if I may, Senator, the most disturbing thing about this debate is that it is characterized by the absence of research and data. And we have been in discussions with the NIH to try and get a better view on what the facts of the matter are. And I would say, without taking a view of either those who favor venture capital participation or those who do not, it would be very helpful if we knew what we were talking about. And I think the program is sufficiently important, the question is sufficiently important that we should encourage the NIH to engage in some research, which I think could be done in a fairly timely manner. It is not that hard, and I am distressed that it has not been done already.

Chair SNOWE. Yes, that is a good suggestion. I know that GAO did a study but did not evaluate the majority-minority participa-

Dr. WESSNER. It may not be a surprise to you, Senator, but we think the National Academies might be more qualified to carry out that study.

[Laughter.]

Chair Snowe. Okay. Thank you. Point well taken.

Senator Kerry?

Senator Kerry. Chair Snowe, thank you very much for accommodating me. I apologize to the witnesses, but there is an amendment on the floor that I need to go and be involved in. Let me press a couple of quick points, and then I will leave some questions for the record, if I can.

Mr. Thorson, just coming to you quickly, first of all, thank you for your testimony and thank you for this oversight, which is important. Senator Snowe has already gone into the fraudulent component, so I will let that stand. But let me address your second point, the contracting officer error. You say that good cases have been undermined by contracting personnel at Federal agencies who do not comply or are just unfamiliar with small business contracting requirements.

Now, how can you be a contracting officer and be unfamiliar with

the requirements?
Mr. THORSON. The small business regulations—well, first of all, you are correct. But, in fact, we find that there are contracting officers who deal regularly with very large corporations and-

Senator Kerry. In which agencies?

Mr. THORSON. Well, I hesitate to name any particular ones because as soon as I do that, I will end up-

Senator Kerry. Well, isn't that your job? Aren't you supposed to name them?

Mr. THORSON. But, there are those who do not know the small business regulations or the 8(a)-

Senator Kerry. Well, that is just a fundamental function of leadership. I mean, if you do not—somebody has got to sit them down and say: Here is the protocol; you do not issue any contract without checking off this list.

Mr. THORSON. Right.

Senator Kerry. This is pretty simple.

Mr. THORSON. Sometimes it is as simple as exactly that, and one—

Senator Kerry. But it does not happen. Why?

Mr. THORSON. I cannot tell you exactly why, but I do feel that part of what we have suggested is—

Senator KERRY. I just find it shocking.

Mr. THORSON [continuing]. That where this happens, the SBA needs to become involved in some kind of training aspect if this is

really the problem we think it is.

Senator Kerry. Why the SBA? Isn't each agency responsible for living up to these standards? You go through a list here, and I applaud you for it. But listen to this: Agencies accepted bids from contractors on small business contracts even though the contractors had not certified that they are a small business.

Nobody who does not certify should even get it, period, end of

Mr. THORSON. Right.

Senator KERRY. It is like going to get a bank loan. Without full disclosure, you do not get it. I mean, this is—it is sort of—I am sitting here and I am saying, "What is going on here?" Other errors have included failing to request size certification from a business.

Mr. THORSON. Right.

Senator KERRY. I mean, there just ought to be a fundamental checklist, and you do not go forward with your application if you do not check off the list. It seems like there is a willing complicity in this process, frankly.

Chair Snowe, I think we have got to ask for something more from the leadership of these agencies and the administration. This is just unacceptable. This is why it goes on and on and on and on. Nobody enforces it. Nobody cares. Nobody puts it in place. This is not a joke.

Mr. Thorson. And this is exactly why we specified these things in our testimony, because a lot of people, if you talk about these things, they just cannot quite believe it is that simple that people cannot follow these particular rules.

Senator KERRY. It is just stunning to me.

Mr. THORSON. And that is exactly why we have put this into the testimony, because we wanted you to see the kinds of things that we find.

Senator KERRY. Has anybody been fired for failure to do these things?

Mr. THORSON. Not that I am aware of. Senator KERRY. Well, they ought to be.

Senator KERRY. Let me continue through your testimony. You say, "What can be done to correct the problems with small business contracting?" You talk about the final regulation. Then you say, "However, it has now been more than 3 years since SBA issues its proposed rule on annual certification."

Mr. THORSON. Right.

Senator Kerry. Three years.

Mr. THORSON. In fairness—and this gets back to what Senator Snowe asked me also—there are a lot of agencies giving input into this, and this is a very controversial element to—

Senator Kerry. Sir, with all due respect, we cannot take 3 years to do these kinds of things. This is what drives the average citizen nuts. This is Washington.

Mr. THORSON. Right.

Senator Kerry. I mean, we cannot do that. Three years to decide about an annual certification, which is accountability.

Madam Chair, I would like to ask you, I think we ought to ask for a deadline from the SBA as to when this is going to be either decided or not decided.

Chair SNOWE. Well, I would concur. I do not think there is any rationale for it, and GAO has, you know, even indicated it could improve certification for small businesses every year. It is very simple.

Mr. Thorson. Right.

Senator Kerry. Finally, you say, "Congress could also establish control processes within the SBA." You know, we cannot—are we going to micromanage? I mean, this is crazy.

Mr. Thorson. Yes, sir.

Senator KERRY. You have to demand this. As the inspector general, you have to require that they are going to live up to the standard, and we in the oversight hearings ought to demand it, and we ought to have an oversight hearing on this and demand it. It is just—you know, I have been around here long enough to understand what can be done and what cannot be, and this is just unacceptable. It is a matter of administrative leadership. You bring your people in, you set the standards, you hold accountability, you measure the standards at the end of a month, at the end of 2 months, and people who do not meet them do not work anymore at that agency. That is how you run it.

Mr. THORSON. Yes, sir.

Senator Kerry. And somebody ought to do that.

Mr. Watson, before I have to leave, I thought your testimony was succinct and very comprehensive, and it was terrific testimony. And I just want to ask you and Dr. Squillante to debate with Mr. Bigger here. It may be inadvisable to get into a debate with a guy by that name, but anyway.

[Laughter.]

Senator Kerry. You described S. 1263 in pretty Draconian terms. It is going to really undo the system. It is going to hurt. On the other hand, Mr. Bigger, you say, American competitiveness is at stake here, we have got a really divergent point of view.

The Chair has appropriately pointed out this later-phase financing with respect to what VC gets involved in and does not get involved in

volved in.

Isn't there a legitimacy to the notion that SBIR is getting people starting up and getting them to a point where, if they have got enough legitimacy and enough credibility in what they are doing, they are going to get VC money; but that you should not undo that

already too small a pot of distribution to those entities that need it by creating competition for VC stage financing.

I am asking that. I am not certain, and I am really trying to figure this out. But it is hard for me to understand how a company that can attract \$78 million worth of VC investment has enough credibility to do that but it cannot go to the next tier with the next product, or whatever it is.

So I want to hear you guys go at it a little bit, if you can.

[Laughter.]

Senator KERRY. I mean, what do you say—you have not responded to Mr. Bigger's testimony, so what is your response to his notion that this is going to hurt American competitiveness?

Mr. Watson. Well, I understand that there is a problem that the biotech people have, which is to bring a pharmaceutical product to market takes tens, even hundreds of millions of dollars. But that is not a role that the SBIR program is equipped to address or satisfy. And if that is a real problem—and I cannot say whether it is or not—but if it is real, it needs another solution, not the SBIR solution.

Senator Kerry. And, Dr. Squillante, you sort of argued the same thing. You agree with that.

Dr. SQUILLANTE. Yes. I think that it is clear that venture capitalist firms have a long, expensive road to go, but it is not what SBIR is about. And it is not the \$100,000 and \$750,000 awards that these companies are after. They are after awards that are 10 times that size. They have access to other funding. They can participate in SBIR if they own less than 50 percent. If they only meet the statutory requirements that everybody else in the SBIR program has to meet, they can own more than 51 percent. And I agree, these venture capital-funded firms have a lot of great ideas that could have an impact on the future health of the citizens of the country. But so do the eight to ten other small companies which will be eliminated from the SBIR program for each one of these very large awards that are awarded.

Senator Kerry. Mr. Bigger?

Mr. BIGGER. Yes, I think what you need to do is really split this thing up in terms of where venture capital puts their money and what other research goes on. And I will speak to my own company, but it goes beyond just my company. I think we are just an example.

Venture capital is basically supporting big ideas that they view as having large market potential, great returns to them as an investor. There are a lot of other programs. For instance, most of my money that I have raised for my company has gone to developing a broad-spectrum antibiotic for the treatment of bacterial infections that are resistant to current drugs. Okay? That is a huge opportunity. I have spent probably \$50 to \$60 million already doing that. I am going to spend another \$250 to \$300 million bringing it through Phase III. So that is where the venture capital money comes in.

However, there are instances, where my technology actually can be used in things other than infectious disease. For instance, tetracyclines now can be use for the treatment of multiple sclerosis. We plan on entering the clinic at the beginning of next year with a potential oral treatment for multiple sclerosis.

How did we find that out? By using grants of \$250,000 to

\$500,000 to do that basic research, not—

Senator KERRY. Well, let me try to get at this a little bit. First of all, we are all anxious to go down those avenues of exploration, and we are all anxious to try to excite as much investment and exploration in those as possible. This is our future. Life sciences is one of the most, hopefully, promising job creators and solid parts of our economic future. But here is the dynamic.

With a small pie to be divided up, is this the best use of that pie from this particular sector of our Government? Or do we need to be thinking in larger terms or a different term or, to pick up on what Senator Snowe said, is there some sort of alternative phase of financing that we might consider being engaged in and then

pulling out of at a certain point? Is there a different way to skin

this cat?

Mr. BIGGER. I actually believe there is. But I also believe that there are some real advantages to using a venture-backed company because there is information that has been developed. You can leverage the infrastructure to do things on other projects that typically would not be funded.

For instance, a lot of the work that goes on in my company, we were able to do it for \$250,000, \$500,000 on these grants because we have leveraged the larger infrastructure that somebody paid

money for from an investment standpoint.

So I think you actually get more bang for your buck when dealing with some of these firms because they have infrastructure, they

can do things that you typically cannot do.

The other piece to this that deals with where the money goes, is that it does go outside of the Boston and California area, I can tell you that we had four SBIR grants. Every one of them involved a university helping us do some of the testing of the drugs (animal testing and in vitro testing). They were done at universities outside of Boston. One of them happened to be in Kansas; the other in Georgia; and one of them was in California.

But, again, there is money that goes into other parts of the country other than just into these two areas, and it goes through, is

funneled through the companies.

Senator Kerry. Well, I appreciate it, Chair Snowe. Thank you for you—

Mr. Watson. Could I add a comment?

Senator Kerry. Yes, sir.

Mr. Watson. SBIR takes 2.5 percent of the total funding; 97.5 percent is at another door. My recommendation is that they look to that other door at the NIH, which NIH is the institute that is affected here. And we have already proposed or we are in the process of proposing a compromise solution that goes in that direction.

Senator Kerry. Well, thank you very much, Mr. Watson. We are interested, obviously, in trying to work this through and be helpful, and I think Chair Snowe and I would like to see if there is a way to get a compromise here that does what we both want to do. We want to excite the biopharma field, and we also want to preserve SBIR's ability to work.

Dr. Wessner, I know you were trying to get a comment in. I am

trying to get to the floor. Competing interests.

I trust, incidentally, when you are talking about Yankee principles, you are talking about Maine and Massachusetts, not the New York—

[Laughter.]

Senator Kerry. Not the New York kind of Yankee. Mr. Watson. I think now I can safely say yes, sir.

Senator Kerry. Mr. Wynn, I cannot stay to hear the answer, but I am interested and maybe you could submit it for the record. I just really want to know what you think we can do to more effectively meet the service-disabled veteran procurement goals. I think that is really important.

Mr. WYNN. By all means, sir.

Senator KERRY. Thank you, sir. I appreciate it.

Chair Snowe. Thank you, Senator Kerry.

Senator KERRY. And thank you all very, very much. And, Mr. Thorson, I just want to say, I think what you did—when we asked those questions of you at your confirmation, whether you are going to draw the line between yourself and the SBA, I think you did that in this report, and we really appreciate it. And I think that is a great start, so thank you.

Mr. THORSON. Well, thank you, sir.

Chair SNOWE. Yes, thank you.

Dr. Wessner, did you want to continue? Did you have any comment to make?

Dr. WESSNER. Yes. If I may, I think the discussion we just had illustrated a point. You know, how many of these firms actually have venture capital? And how many of these firms have what sort of venture capital? And how many of them are working on the same thing for which they have the venture capital?

I could go on, but I think you take my point. It is just simply we do not really have a very good grasp of the parameters of this

issue.

Chair SNOWE. You know, it is an interesting question at this point as to whether or not we defer consideration of any changes until we can get a factual report that indicates exactly, you know, what are the numbers, who is participating, you know, how would it affect the whole program. And I think that is the question.

On the other hand, SBA has made a decision, and, you know, we are concerned because, obviously, there is a difference of opinion on this committee. But I do not think it is, you know, so far apart that we cannot, you know, sort of resolve those issues. And the question

is whether or not we proceed with that now.

For example, Mr. Bigger, on the question of having venture capital participation, you know, with venture capital companies, not individuals, what about—as I think even Dr. Zerhouni said at the NIH, indicated in a letter that just having that requirement, allowing that requirement for venture capital participation, but to comply with the small business affiliation of 500 employees or fewer, how would you react to that?

Mr. BIGGER. Well, I think if you look at most venture capital groups, they are relatively small organizations. There are a few large ones. But in general, they own somewhere between 5 and 20

percent of a company they invest in, and even if you probably added up all the people that work in the venture capital companies that have invested in my company, you probably could not even come to 500 people, combining the employees of Paratek and all the investors employees. Venture capital people have a difficult time within their own firm agreeing on plans and coming up with the direction they would like to take with a company, never mind trying to convince 10 other venture capitalists to all agree in terms of the directions of where their company could go.

So I just do not think you can look at a venture investor as a big company. It is not. It is really individuals within a company who come and observe board meetings or participate on a board. It is not an organization of hundreds and hundreds of people, as venture capitalists are small organizations. And they do not run my company and their involvement in my company is not very different than they are with some other portfolio companies. They may have 20 companies in their portfolio, each one having a dif-

ferent area of expertise or whatever the case may be.

Chair SNOWE. Well, but they do have the ability now—I mean, NIH, for example, has the ability to waive the guidelines. DOD does. They can go to SBA to waive the guidelines. I think, Mr. Watson, you indicated—isn't it 70 percent of the NIH grants that went to—

Mr. Watson. Were in excess of the guidelines.

Chair SNOWE. Yes, were in excess of the guidelines, have gone

above the guidelines, so there has been that flexibility.

You know, Dr. Wessner is right. We do not have the facts on what companies and what size and so on, and that obviously would be very useful in this discussion. But what we do not want to do is to really undermine the original intent of the program when it was, you know, established, which was to allow the entrepreneur the innovation that needs—you need to nurture that, because otherwise that will be overwhelmed if, you know, potentially large companies can be involved in this process and, you know, change the form of the program. And it ultimately could. It could change the whole direction. I think it is a question of where do we find, you know, the right balance in this program to ensure that you get both. But at the initial stages, you certainly want the small business and you want to be sure that it is not always concentrated in just a few States across the country. I mean, very few States have large venture capital firms. You know, my State has maybe one or two small ones. But most of the, you know, venture capital is concentrated in very few States, about 10, as I think Dr. Squillante's testimony indicated, that about 85 percent of it in 10 States. That is a major concentration.

Yes, Dr. Squillante?

Dr. SQUILLANTE. Thank you. And following up on this point, I think that the question of affiliation and size is an area where we almost certainly have grounds based on these comments, where we can move forward on a compromise.

I do want to point out that Senate bill 1263—take for granted that, let's say, you need to change SBIR. Let's assume that. That is not what Senate bill S. 1263 does. It does not change the rules on affiliation or numbers. What it does is Section 3 of that bill very

specifically waives those requirements for venture capital firms. And to do that is to set special rules for a special group of people,

and that is definitely wrong.

Mr. BIGGER. I think that that is where a compromise could be reached. I think it is important to understand that, you know, a lot of the research that is being done by companies like Paratek and so forth are truly entrepreneurial. You know, they are venturing into areas that venture capitalists are not going to put money into. And if you look at where venture capital is located, it is pretty much where all the major money markets of the country are and the world are. And so you just need to follow the money and find out where they are going.

But if you attend a biotechnologies annual meeting, you will find that almost every State in the Union now is trying to attract biotechnology into their State, and they are very seriously trying to utilize the universities to do that. And I think it is a great way, and that is how I think you are going to get some diversity in terms of where money goes into States such as Wyoming and other States that do not right now have a lot of venture capital money.

But I think it is unfair to exclude a company, just because you have venture capital investors. In order to develop a big drug for different diseases today, it takes a lot of money right from the beginning. And you can literally just by starting a company be over the 50-percent ownership of venture capital, and you have not done

anything at that point in time.

So I think there has got to be some way to define what the affiliation needs to be or that type of thing, and not just make a blanket rule that says any venture capital backed company that is 51-percent owned should not be that way. Because today, based on the rules, Madam Chairman, I could license myself as a management group, can start a new company, and call it Bigger Pharmaceuticals, license the technology out of Paratek, and then apply for a grant back to SBIR, have all the work done at Paratek, then give a royalty-free license back to Paratek, and no one would be the wiser. I would be legal in terms of what I did. But I think that is not what the intent of the law is or intent of what Congress wanted.

I think it is important that we somehow compromise as to where we are and how we can maximize the money that the NIH has through the SBIR program. How do we maximize that? And I think it is a win-win for both groups. You know, I think we have a difference of opinion as to affiliations and venture capital. But I think in the end we are trying to improve the innovation and where the United States stands in terms of innovation worldwide.

Chair SNOWE. Well, would you agree with the affiliation requirement that they be 500 or fewer, the small business affiliation requirement?

Mr. BIGGER. But, again, how do you define that with multiple VCs that have multiple companies they invest in—do you combine all of their portfolio companies employees and say that is the 500?

Chair SNOWE. We obviously would have to come up with a definition?

Mr. BIGGER. Yes, I think that that is a way to go that would not penalize some small companies. Paratek is a 66-pension company

which has had to return three SBIR grants that, believe me, would not be funded by venture capital—one for the treatment of anthrax, one for the treatment of malaria, and another treatment for spinal muscular atrophy. But I have been forced to return the grants. And I think it wrong that because Paratek is 55-percent owned by venture capitalists, it does not qualify as a small company.

Chair SNOWE. These are not because of individual investors?

Mr. BIGGER. Yes, 45 percent of my investor base is individuals. If you look at it in terms of U.S. investors, including VCs and so forth, I am probably in the 65 percent range. So easily qualifying for the SBIR, but unfortunately, the 20 percent of the venture capital is not included because they are not individuals.

Chair Snowe. Yes, Mr. Watson?

Mr. Watson. I would like to remind everyone of the longstanding eligibility requirement that says "independently owned and operated," and that has been the criteria. And I think it should stay that way.

Chair Snowe. In the Small Business Act, yes.

Mr. Watson. Absolutely.

Chair Snowe. Yes. Dr. Wessner?

Dr. Wessner. Just again a small observation. I think the line of questioning you have is intriguing. It underscores the need to know the dimension of the issue, as I have mentioned. But also one of the points that I think is relevant that we documented in this first volume is maintaining the flexibility of the program. You may want to—if the numbers are not large, there may be an opportunity for the agencies on a case-by-case basis to ask for some exemption. But that simply illustrates why we need to know more about the dimensions of the issue, my point being there may be some happy middle ground where we could work through that.

Chair SNOWE. I appreciate that. Yes, we try to find them these

days, although not easy.

Dr. Wessner, while we have you here, I wanted to ask you, obviously you spoke, I think very eloquently, to the value of this program and how, you know, other countries are emulating this program and possibly go beyond it. The Office of Management and Budget on their expectmore.gov website indicated that over half of the SBIR program has not demonstrated results.

Can you speak to that issue at all? Do you think that OMB has the resources, the expertise to conduct the kind of quality assess-

ment that is required?

Dr. WESSNER. Thank you, Senator. You ask penetrating but complicated questions there. I am not prepared to discuss specific recommendations of the Office of Management and Budget for reasons that you would understand. I think the question you are asking is a perfectly valid one. One of the things that we have documented here—and I do not mean to be self-serving, but this is the methodology that we are employing and it is public.

There is sometimes the risk that an agency takes a view, and I think institutionally it is important to understand—and this is a personal opinion, not an Academy opinion—that the Office of Management and Budget likes a program that is in the budget that it manages. And the SBIR is not. So I am not sure you can institu-

tionally expect love and affection from OMB with regard to this program.

Chair Snowe. It may not be the exception, either.

[Laughter.]

Dr. Wessner. If I may, let me just very briefly, if I could, in a few paragraphs answer your question. One of the things that you have to recognize when they ask whether there has been significant accomplishment is the diversity, first, of what they are trying to do. Different agencies have different missions. They have different philosophies. They have different types of topics. They have different roles in the solicitation. And they have different expected outcomes. NSF is trying to do something dramatically different from the Department of Defense, and when we find those grouped—and if I am not mistaken, you may well be quoting from one of the studies of Defense. So there is this wide variety of things.

When we say is it commercially a success, well, again, without trying to—what do we mean by "commercial success"? For example, if a firm comes up with a new and better nuclear trigger, do we really expect that to be sold widely commercially? Well, probably

not. We would not want to encourage that, I think.

It is important to keep in mind that in some cases you can have a very significant accomplishment by the program in a Phase I. They answer the question. In some cases, they can come up with an algorithm that can have important security accomplishments, but the \$100,000 Phase I solved that, done. There is no commercial—no apparent commercial application afterwards. And that illustrates an underlying problem. We talk about SBIR, but within the agencies these things are not stamped "SBIR." As one researcher put out, there is no SBIR shrine either in the agency or necessarily in the company.

I think one of the points that was illustrated is often a series of awards go to build a capacity in a company where the company then does something different than the project. So we can come along with our researchers: Did your project work? Were there any sales? No. If we do not ask anything else, he will not tell us, Oh, but that actually enabled us to do the thing we did succeed with.

I do not want to be, seriously, an apologist for the program. Things can be improved. But it is very important to understand the complexity of what we are asking. And if I may just illustrate that with a recent real experience down in New Orleans with Governor Blanco, a very distinguished and intelligent State official from Virginia turned to me just before I spoke, and he said, "Does this program really work, do you think?" And then he got up and he wanted to talk about the new developments in Southern Virginia by a company called Luna Innovation—which, of course, was funded by SBIR. And I think that illustrates the sort of gap that we sometimes get.

You know, "It is my company, that one worked. But does the pro-

gram work? I don't know."

So that type of thing I think has to be taken into account, and we will hopefully document it. But sometimes I think emulation, as I discussed earlier, is the highest form of flattery for a program and the fact the rest of the world is doing it may suggest we are on to something.

Chair SNOWE. And I think you make the point that you have to measure the original goal, and it is in our interest and the Federal Government's interest to encourage and nurture this culture for, you know, R&D that otherwise the Government cannot do, but to support it and hope the innovations can be, you know, applied, you know, whether it is in DOD or elsewhere, Department of Energy and so on, but in the commercial sector as well, depending on what it is all about. But I agree with you—or a pharmaceutical. So, I mean, it is in our interest, and that is not measured, I think, by OMB. It just looks at the end result of whatever it is but not where it ends up going or, you know, what was the original purpose.

Mr. Wynn, a final few questions here. On veterans contracting, do you think that there should be a formal certification for service-

disabled veterans?

Mr. WYNN. Chairman Snowe, that has been discussed among the veteran business community, and right now it is being supported by many of them to use the Department of Veterans Affairs to come up with a certification program for service-disabled-veteranowned businesses.

Chair SNOWE. And I think it is unfortunate about dismantling the Office of Federal Contracting Assistance for Veterans and the Advisory Committee as well for Veterans Business Development. So I gather you are recommending that we ought to reverse those decisions?

Mr. WYNN. Well, we would like to see more Federal contracting support for veteran business owners out of the SBA, whether it be that office or now they are talking more about the Office of Veterans Business Development, which had already been there but had not been providing a great deal of assistance in Federal contracting. So we would like to see more support from there.

Chair SNOWE. Is that what you are recommending, 23 to 28 per-

Mr. Wynn. Yes, ma'am.

Chair SNOWE. Yes. It may be a challenge, but I understand why you are recommending it. And I think that obviously we are going to have to really concentrate on, you know, what has gone wrong, as a matter of fact, in providing more support for our veterans, frankly, you know, especially when they return from, you know, serving in Iraq and Afghanistan, a lot of them small business owners and coming home. We need to provide them the assistance that they deserve, getting back on their feet and making, you know, that transition as well.

Mr. Wynn. Could I make a comment on one other thing, too, if I may? If it is in some way possible to eliminate what we call the Rule of 2 to provide more ease of contracting with service-disabled-veteran-owned businesses, we believe that this would really increase the number of contracts awarded to service-disabled veterans. And it should not, in the opinion of many, be very difficult to do that.

Chair SNOWE. Okay. Thank you.

Mr. Thorson, we just got a response from SBA that e-mailed us that on the 3-year delay of the rule, they are saying it is because the SBA inspector general—obviously not you since you just arrived, so you can breathe a sigh of relief. But what is the issue here? Because, obviously, we want to get to the bottom of it, and I think it is going to be absolutely essential that we do. But, you know, what would be the justification for their suggesting that it is the inspector general's office that is delaying the rule?

Mr. THORSON. I am sorry, ma'am. For some reason I am having

trouble hearing you. I apologize.

Chair SNOWE. Okay. The SBA e-mailed us saying that the delay in the promulgation of the rule, you know, that has been delayed for 3 years was because it was held up by the SBA's Office of Inspector General—not you, of course, because obviously you just arrived, but obviously the previous inspector general.

[Pause.]

Mr. Thorson. Obviously, I was not involved in that at this time so I am not real sure, but we do circulate those internally. But I really have a hard time understanding that they feel that we held that up.

Chair Snowe. Right.

Mr. THORSON. That is not our position.

Chair SNOWE. So you do not have any idea why they would have suggested—why the inspector general's office would have been responsible for that?

Mr. Thorson. No.

Chair SNOWE. Okay. Well, obviously, we need to get more answers, and I think very aggressively so on these issues. I am very disturbed, frankly, by the violations of law, the fronting of companies. We have got, you know, large businesses that are fronting the small businesses, you know, replete with examples, and also the fact that people are just, you know, continuously violating flagrantly contract bundling. And we are just going to have to get to the bottom of it. And I think that have strong penalties in law and setting examples for prosecution is going to be essential. But I am just very—and even some very well established contractors, you know, have been named by the GAO as potential beneficiaries of fronting. I mean, they are fronting small businesses, I mean major contractors, which I think is extremely disturbing, and it just shows to me a flagrant violation and dismissive attitude, you know, about what the rules and regulations, not to mention the statute requires.

So I am going to explore a legislative solution, and I think that your office should continue investigations regarding these issues. And I would do it immediately because we would like to move forward in trying to get to the bottom of it and we are able to make

sure that this does not continue, this pattern of behavior.

Mr. Thorson. Right. And to go back to Senator Kerry's point for a minute on the contracting error, when you involve the people from other agencies, that obviously hinders our ability to go into that. So we have been working with the other IGs and actually have created a Small Business Review Guide in order to help the OIGs of other agencies to be able to look at these situations as well. And I think that helps to address what Senator Kerry was talking about as well.

Chair SNOWE. Well, I agree, you know, and their statement that they submitted last night says that SBA's ongoing review of the underlying is that firms receiving these contracts were legitimate small businesses at the time of the award but great to be large or were acquired by large businesses over the life of the contract. And I am thinking, well, how long is the contract? I mean, that would all have to happen sort of quickly.

Are you familiar with that argument? Are you, Mr. Sims? Have

you heard that one before?

Mr. Sims. Yes, I have heard that. But if you think it is bad for small businesses, when you get to minority businesses it is even worse.

Chair Snowe. I can only imagine.

Mr. Sims. I spent several months with folks at SBA looking at a third-party certification program. At the end of that 7 months, somebody was transferred over—and this was in the last administration—from the White House, who sat in the room and designed a third-party certification program on their own with no experience. And when they had the bidders conference, there were only two organizations that had certification experience in the room: NMSDC and WBENC, the Women's Business Enterprise National Council. Everybody else was a minority supplier looking at a revenue stream, and the certification program set up by ŠBA was a failure. At one point they expected after the first year 30,000 businesses in their database. They had 3,000. They had to go to the Department of Transportation and get their folks and other agencies because it was an abysmal failure.

Two years ago, they did another RFP on third-party certification. Ten days before they applications were due, they pulled it off and canceled it. And they recently, last year, came up with another third-party certification attempt. But the only people eligible were 8(a) firms. And so the craziness is that the notion of having one 8(a) firm looking at your financials, looking at your customer base, and then determining whether you are eligible, that is why I said there is chaos and turmoil over SBA. And I am not surprised at the tap dance of saying it is the inspector general's office that is holding this up. It is not surprising. Chair SNOWE. Okay. Mr. Thorson?

Mr. THORSON. It was a little surprising to us.

[Laughter.]

Chair Snowe. Welcome to your job.

Mr. THORSON. The point that you also made as far as the companies growing and being recertified as to the issue of 1-year recertification is controversial and we know that. I mean, there are positions that break down politically. There are positions that break down in any other ways as well. But the truth is, if you use that, that gives you the tightest rein of control on this. And whether companies are growing large or not, it really comes down to, with annual certification, you really do exercise a much better element of control.

I think it also affects, frankly, some of the errors that we are talking about, and I keep coming back to Senator Kerry's question because I was taken aback by it because it was such an obvious one. Well, how can you not realize as a contracting officer that somebody has not certified one way or another? That was a hard question to answer. I do not know.

Chair Snowe. It was too logical, that is why.

[Laughter.]

Mr. THORSON. And so those are the kinds of things that I think if the certification is required more frequently to the point of annu-

ally, then I think you do eliminate a lot of these things.

Chair Snowe. I would agree with that. I think that is absolutely right. I think that is obviously a frustrating point, and I think we recognize some of the changes that need to be made very shortly, and I appreciate it. And I know it is frustrating, but I think you understand the tasks at hand in your department, do you not?

Mr. THORSON. Yes. Chair SNOWE. That is right. It is a great initiation. But I think that this is a good way to start in understanding the dimensions of the problem, hearing others here today speaking to these questions, and we would like to tackle it very shortly, if possible, and do as much as we can in the reauthorization, which we expect to accomplish by the end of this month. But, you know, so we hope that we can get your input to the degree that you can, and others' as well, as we proceed on these questions.

I would also like to say that Senator Enzi had to meet with the leaders and that is why he had to depart, but I am going to submit

questions on his behalf as well.

I appreciate your input, your patience, your testimony, your guidance here today, and also sharing your perspectives of your experiences and background. It has been very helpful, and I am hopeful that we can resolve some of these questions here before this committee on these vital programs that certainly can and do make a difference. And we want to make sure that we can preserve the integrity of them as well. So I thank you all for being here today and for taking the time to participate and testify before this committee.

With that, the hearing record will remain open until the 14th of July for any additional questions or comments or testimony. In the

meantime, this hearing is adjourned. Thank you.

[Whereupon, at 12:53 p.m., the committee was adjourned.]

APPENDIX MATERIAL SUBMITTED

Statement of Sen. Burns Senate Small Business Committee Hearing July 12, 2006

Thank you for calling this hearing today to discuss the importance of the SBIR program and improving federal contracting opportunities for small businesses.

I strongly believe that the SBIR program is essential to the continued growth of our economy. Montana is a small business state that thrives on the entrepreneurship of small business. We must to make sure that the Small Business Administration and the Small Business Innovation Research Program continue to help Montana's, and the nation's, small businesses.

One of the concerns that must be addressed by this Committee is the number of loopholes that provide small business assistance to what truly are large businesses.

When large businesses benefit from this help, it is at the expense of smaller ones who most need it. In fact, these small businesses are the engines of our economy, providing cutting-edge research and product development. In Montana, the Bozeman area is thriving due to this type of investment. Montana State University has worked with local business incubators to turn students' ideas into profitable businesses. The SBIR program, particularly through the Department of Defense and NASA, have provided much needed seed capital and support to this fledging businesses. This typifies how the SBIR program should work—companies with little access to outside capital should have an opportunity to develop their product, which could be equal to or better than one produced by a venture capital-backed small business. We should keep these goals in mind, especially in light of the upcoming SBA Reauthorization bill this Committee will consider.

The SBA does not need to reform the SBIR program but instead further its development. I appreciate the testimony from the witnesses today.

RESPONSES BY ERIC M. THORSON TO QUESTIONS FROM SENATOR JOHN F. KERRY

Question 1. Contracting Officer Failure. In your response to my question regarding the failure of contracting officers to comply with small business contracting requirements, you stated that you do not know why this occurs, that you can not unquirements, you stated that you do not know why this occurs, that you can not understand why this type of negligence is allowed to continue unaddressed in Federal procurement procedures. You also commented that you have been working with Inspector Generals of other Federal agencies to remedy the problem.

• Will you formally commit to looking into this issue, and providing the SBA with

recommendations on how this issue can be addressed?

Answer. The OIG's Management Challenge 1 identifies that errors by contracting Answer. The OIG's Management chaining is included in the Agency needs to address to improve small business contracting opportunities and prevent the performance of small business set-aside contracts by large businesses. Action Item 4 in that Challenge tasks SBA to "Develop and take steps to provide reasonable assurance that agencies are providing adequate training to contracting personnel on small business contracting procedures." We are working with the Agency on steps to increase training that is provided to Federal working with the Agency on steps to increase training that is provided to Federal contracting personnel. In addition, we have developed a small business procurement guide and provided that guide to other agency OCCs to proceed that a small business procurement guide and provided that guide to other agency OIGs to encourage these offices to assess compliance with small business contracting requirements in procurement audits. We will continue our efforts to look into the reasons for contracting officer error and work with SBA to identify additional recommendations to solve this problem.

Question 2. IG Role in Closure of the SBA Veteran's Contracting Office. In May, the SBA made the determination to close its Veteran's Contracting Office. This office served a vital need to the service disabled veteran small business community, and the decision did not sit well with the community.

To what extent was your office aware of the decision to close the office?

Since the office was shut down, has there been any effort to look into the impact

of the decision? If not, do you intend to do this?

Answer. Our office was not consulted on the Agency's plan to eliminate this office and did not become aware of the closure until after it was reported by the news media. We have not looked into the impact of this decision because the office, prior to its closure, had a staff of only one person, and because agency personnel have advised that the functions of that office are being transferred to the SBA Office of Veterans Business Development. Given our understanding of this matter, we do not plan to open a review of this decision at this time.

Question 3. Relationship with New Administrator. In his confirmation hearing, Administrator Preston spoke to the importance of maintaining the independence of your office, and about his intention to work with you as a partner in policing and improving operations at the SBA.

• Has the new Administrator approached you about his intention to work closely

with you and to enforce your findings and recommendations?

• Has he stated his intention to follow through on any of the recommendations made with respect to improving the SBA's ability to serve as a watch dog for small

businesses in Federal contracting?

Answer. I have met several times with Administrator Preston, who has advised that he values and respects the contributions of the Office of Inspector General and plans to work closely with my office in implementing OIG recommendations. I have presented our concerns regarding Federal small business contracting to Administrator Preston, and I am greatly encouraged by his significant level of interest in this important subject. We will continue to work with the Administrator to implement the OIG recommendations in this area.

Question 4. Implementation of Women's Procurement Program. The SBA has dragged its feet for 6 years following Congress's enactment of a women's procurement program. Although regulations have been issued and are under review, there is some doubt expressed by the women's small business community as to whether this program will ever be implemented.

Has your office looked into this delay and the reasons behind it?

What is your understanding of why this program has not been implemented,

and what can be done to ensure that it is?

Answer. We are generally aware that the Agency has had studies performed regarding the nature of industries for which it would be appropriate to encourage women-owned business contracting, as required by Public Law 106–554, Section 811(m), and has issued for comment proposed regulations to implement the Women's Procurement Program. Beyond this, however, my office has not looked into the issue of the delays in the establishment of this program. The Agency would be in the best position to respond to questions about the timing of the program.

RESPONSES BY ERIC M. THORSON TO QUESTIONS FROM SENATOR CONRAD BURNS

Question 1. SBIR Program.

1. What efforts are underway at SBA, if any, to monitor SBIR awards given to venture-capital backed firms? Based on a recent GAO study, much of the impact of VCs occurred in NIH. What impact has this had on non-VC-backed SBIR applicants?

2. Has the SBA considered, as some states have implemented, a Phase 0 award, as a precursor to Phase I?

Answer. My office has not looked into these issues. The Agency would be in the best position to respond to these questions.

RESPONSES BY JOE WYNN TO QUESTIONS FROM SENATOR JOHN F. KERRY

Question 1. Closure of the SBA Veterans Contracting Office—The SBA decided in May to shut down the Veterans Small Business Contracting Office, which at the time had a full-time staff of only one. Given the Administration's stated commitment to veterans, this decision seems like another example in a line of decisions to save pennies on the dollar at the expense of an entire underserved community.

• Can you speak to how this decision affects the veterans community of small business owners?

• What services were provided through this office, and how are veteran small business owners adversely affected by the decision?

Answer. The decision to dismantle the Office of Federal Contracting for Veteran Business Owners affects the veteran small business community tremendously. It leaves a void in a program that is still in its infancy and sorely needs a leader to ensure its implementation. While the Task Force for Veterans Entrepreneurship has been voluntarily performing the role of advocacy and oversight of the Veterans Procurement Program, as defined by PL 108–183, long before 2003; it was believed that the SBA, with the appointment of Ms. Lewis as an Assistant Administrator to this newly created office, had accepted its role as the Federal agency to ensure compliance.

But after a whole year of operation, SBA never provided any additional staff to work with Ms. Lewis, and later reassigned her to other duties. While it may very well have been the prerogative of the new SBA Associate Administrator of the Office of Government Contracting to reassign the duties under her purview, it's appalling to find that Ms. Lewis was forced to abruptly change her career and receive a reprimand as a result after doing so much with so little. (Many TFVE members request that your office seek to remedy any wrongful complaint or persecution of Ms. Lewis).

that your office seek to remedy any wrongful complaint or persecution of Ms. Lewis). By restructuring the office, the SBA essentially took away an experienced contracting professional; who also happened to be a female veteran with years of experience with the SBA Minority Business Program and one who also participated in the development of the implementing regulations for the Veterans Procurement Program. Such an individual will be hard to replace. Ms. Lewis' dedication to the ideals of the program and proactive initiatives to educate agency personnel and veteran business owners were without parallel. She not only helped to match SDVOBs with procurement opportunities, she also was persistent in encouraging agencies to comply with the law.

Below is a list of the primary services that were provided by the Office of Federal Contracting for Veteran Business Owners:

- Outreach to the veterans community, participating in small business and veterans' conferences, and providing information about the Veterans Procurement Program under PL 108–183 to SDVOBs.
- Provide briefings to agency procurement officials and contracting officers on the implementation of Section 308 of PL 108–183 of the Veterans Procurement Program.
- Oversee the implementation of each agency's strategic plans as defined by Executive Order 13–360 and report on their progress or lack thereof.
- Provide information about filing a protest if a contract is awarded to a small business that has misrepresented itself as a SDVOB.
- Coordination of SBA business development resources for veterans interested in starting or expanding a small business for Federal contracting.

If the Veterans Procurement Program is to be successful, it has to have ownership by some agency or entity that will ensure that agencies are doing their best to meet the mandatory procurement goals. Oversight and accountability is necessary, whether it comes from the Office of Federal Contracting for Veteran Business Owners or

some other agency.

This program is not just about Federal contracting to another preference group. It's about providing for those "who have borne the battle." As was referenced in the Congressional findings of PL 106–50, "the United States has done too little to assist veterans, particularly service-disabled veterans, in playing a greater role in the economy of the United States and thereby must provide them with additional assistance and support to better equip them to form and expand small business enterprises, such that they may realize the American dream that they fought to protect." The program needs a parent and a Champion to lead the cause!

Question 2. Procurement Goal—As you stated in your testimony, the Veterans Benefits Act of 2003 made it mandatory for Federal Agencies to meet the goal of 3 percent procurement for service disabled veteran small businesses. Yet, despite instituting a set-aside program for this community, year-after-year the Federal government falls woefully short of attaining this goal. Last year, only .38 percent of Federal contracts went to service disabled small business owners.

• What explanation is given by the Administration to the service disabled commu-

nity for the inability to reach this goal?

• What is the SBA doing to implement the Service Disabled Veterans Procurement Program under PL 108–183 and Exec Order 13–360?

• You presented several proposals to fix this problem that could be accomplished legislatively. Please explain how SDVOBs would benefit from eliminating the "Rule of Two" and how a level playing field could be created among SDV, 8a, and Hubzone

• What steps could be taken immediately by this Administration, in terms of staff-

ing increases, outreach, etc. to ensure that these numbers increase?

Answer. From the perspective of the Federal contracting community, the OSDBUs, the Contracting Officers, and the Procurement Officials, PL 108-183 provided the contract vehicle that was missing in the previous legislation, PL 106-50. But even with the authority to restrict competition to SDVOBs, agency representatives say they are still unable to meet the goals because (1) they are unclear about the application of certain parts of the statute, i.e. when to use sole source versus when to use set-asides; (2) conflict over the use of "may" set-aside contracts for SDVOBs versus "shall" set-aside contracts for the 8a and Hubzone programs; (3) locating capable and qualified SDVOBs is too difficult and there is no directive to assist SDVOBs with business development; (4) many construction contracts are large so very few SDVOBs meet the bonding requirements; and (5) many contracting officers still don't know the SDVOBs that are out there.

While there may be some validity to these reasons for not meeting the goals, it appears that the SBA is doing very little to help remedy the situation. They were directed by Executive Order 13–360 to (a) designate an appropriate entity within SBA to coordinate with the Veterans Affairs' Center for Veterans Enterprise, to provide information and assistance to SDVOBs with Federal contracting, (b) advise and assist heads of agencies implementing their strategic plans to increase contracting opportunities to SDVOBs; and (c) make training in Federal contracting law, procedures, and practices available to SDVOBs. But as was mentioned in response to question 1, the SBA started an office to assist veteran business owners with Federal

contracting, but then dismantled it less than a year later.

Since the designated agency to assist veteran business owners with Federal contracting, (the SBA) is lacking in its responsibility, it is hoped that the Senate Small Business Committee will support recommendations for the following legislative solutions: (1) Eliminate the "Rule of Two"; (2) create "Equal Parity" among the use of SDV, 8a and Hubzone programs; and (3) provide a "Price Evaluation Preference" of

10% for SDVOBs in acquisitions conducted using full and open competition.

The Rule of Two as introduced under PL 108–183 is contained in Part 19 FAR, and the Code of Federal Regulations (CFR) 13 CFR, Part 125. The Rule of Two states if a contracting officer knows of two or more SDVOBs that can do the work, then the requirement must be competed and a sole source award cannot be made. If sole source cannot be made, then the requirement may be competed among

SDVOBs only under restricted competition.

As stated in my testimony, contracting officers are often under pressure to get certain requirements awarded quickly, especially in the last two months of the fiscal year, and although there may be a SDVOB that can do the job, they routinely go to an 8(a) company using the non-competitive (sole source) authority under that program. Thus 8(a) firms can be rewarded for their self-marketing activities under FAR Part 19. There is no such authority under the SDV Program. In these cases, the Government does not have time to even consider restricted competition among SDVOBs because of time factors.

Elimination of the Rule of Two under the SDV Program is also cited in recently passed legislation, HR 3082, "Veterans Small Business and Employment Promotion Act of 2006", Title I, Section 101, subparagraph (b) "Use of Non-competitive Procedures for Certain Small Contracts," which states that, "a contracting officer . . . may use procedures other than competitive procedures . . . for an amount less than the simplified acquisition threshold." And subparagraph (c) "Sole Source Contracts for Contracts Above the Simplified Acquisition Threshold," which states that, "for purposes of meeting the goals . . ., a contracting officer . . . may award a contract to a small business concern owned and controlled by veterans using procedures other than competitive procedures.

The technical changes to the Small Business Act to eliminate the Rule of Two

from the SDV Program could be made in the following manner:

In subparagraph 36(a)(1) of the Small Business Act (15 U.S.C. 657(f)(a)(1)), strike the last portion of the subparagraph that reads: "and the contracting officer does not have a reasonable expectation that 2 or more small business concerns owned and controlled by service-disabled veterans will submit offers for the contracting opportunity." The remaining subparagraph 36(a)(1) will read: "(1) such concern is determined to be a responsible contractor with respect to performance of such contract opportunity;

To create Equal Parity among the SDV, 8a and Hubzone programs, is to give the same level of precedence to each. At present, many contracting officers consider the authority that says you "Shall" before those that say you "May" with regard to preference programs for small business contracting. So more contracts continue to go to the 8a and Hubzone programs before being considered for the SDV program. The order of priority for contracting preferences among the three groups should be equal. The technical changes to the Small Business Act to create this Equal Parity could

be made in the following manner: Amend subparagraph 36(a) of the Small Business

Act (15 U.S.C. 657(f)(a)(1)), by striking "may" and inserting "shall."

As for the Price Evaluation Preference, it could be implemented in the following manner: Beginning on the date of enactment of this Act the head of each Federal agency shall extend a 10 percent price evaluation preference in full and open competitions to any small business concern owned and controlled by service-disabled veterans. By eliminating the Rule of Two, creating Equal Parity, and implementing a, Price Evaluation Preference, the SDV Program would be strengthened by increasing contract awards, resources, and support without including SDVOBs into the 8a program. The 8a program was created to help alleviate the more than 100 years of wrongful discrimination and exclusion of minorities from the full benefits of American society, including the Federal marketplace. The SDVOB program is intended to be inclusive of any American who served in this country's armed forces, guard or reserves. The SDVOB program should retain its own identify for "those who have borne the battle.'

In addition, there are steps that could be taken by this Administration now to increase the number of contracting opportunities to SDVOBs:

• More outreach to veteran and veteran business community. Create more opportunities to build relationships between agencies, primes, and SDVOBs.

- Require contracting officers to certify as to knowledge and implementation of the Service Disabled Veterans Procurement Program. The senior designated official under the agency's strategic plan should be the Chief Operating Officer or some other such official who also has command authority over the Chief Operating Officer. Managers should have written in their performance evaluations, progress to-ward SDVOB goals and should not receive any bonus, merit increase, or Presidential award.
- Provide funding to non-profit, Veteran Service Organizations within the community to educate, train, and assist veterans interested in participating in the Federal marketplace.
- Comply with the President's Executive Order 13–360 in its entirety. Complete the required Strategic Plans, evaluate their effectiveness on at least a semi-annual basis, and provide semi-annual reports to the public.

• Increase the use of Mentor-Protégé Programs.

 Encourage and support the use of teaming and joint ventures among SDVOBs. Also recognize the past performance of the team and not just the past performance of the SDVOB prime.

• Increase the use of the SBA Commercial Marketing Representatives and the Prime Contracting Representatives for the Subcontracting and Prime Contracting

Question 3. Certification—Discuss your position on the need for a certification program for SDVOBs and who should administer it.

Answer. What is being referred to as a Certification Program for Service-Disabled Veteran Business Owners is really intended to be merely a "Validation and Verification" process. It is recommended that the status of the individual claiming to be a service disabled veteran be verified by the Department of Veterans Affairs and not by the SBA. The VA or DOD would provide documentation to validate the veteran's disability status and the percentage of disability compensation.

It is not recommended that the VA take over the role of verifying a businesses

eligibility to operate as a small business based on size or number of employees. Nor is it intended that the VA should verify the eligibility of ownership or business formation. Since SBA has already been performing small business certification func-

tions, it is no reason why they should not continue to do so.

Question 4. Subcontracting—Since large Prime contractors are also failing to subcontract a minimum of 3% of their work to SDVOBs, what can the agencies do to increase subcontracting opportunities to SDVOBs and to improve the performance of large Prime contractors

Answer. To increase subcontracting opportunities to SDVOBs, large Prime contractors must be held accountable for failing to comply with the subcontracting plans submitted as part of the contract proposal and award. Compliance with the plans should be reviewed by the Contracting Officers and OSDBUs on a quarterly basis with the results reported and made available to the public.

Prime contractors who consistently fail to meet their subcontracting goals, should receive negative past performance evaluations and be required to correct any subcontracting defaults prior to any approval of contract options. Primes who consistently meet their subcontracting plans should be rewarded by receiving priority in future contracts and positive past performance evaluations.

Prime contractors should be encouraged to participate in mentor-protégé programs

with SDVOBs and those that do, should be given an incentive for doing so.

We believe that prime contractors who blatantly disregard making a good faith effort to submit or implement subcontracting plans as required, should be barred from Federal contracting for a certain number of years and liquidated damages should be imposed if applicable. However, this is unreasonable and would be deleterious to the United States. Oversight should be established to ensure that Small Business Plan requirements in the Small Business Act, are carried out by Contracting Officers. Contracting Officers and OSDBUs should be held accountable for reviewing, reporting and enforcing compliance with the subcontracting plans.

Question 5. Survivorship—Presently, a SDVOB will lose its preference status if the SDVOB majority owner passes and the new owner is not a SDV also. How is this issue impacting the SDV community? Please explain your position on whether a firm should maintain its status as a SDVOB after ownership passes to a non-SDV owner.

Answer. We propose the following legislation:

Treatment of Businesses After Death of Veteran-Owner-

- (1) If the death of a veteran causes a small business concern to be less than 51 percent owned by one or more veterans, the surviving spouse of such veteran who inherits ownership rights in such small business concern shall be treated as if the surviving spouse were that veteran for the purpose of maintaining the status of the small business concern as a small business concern owned and controlled by veterans for the period described in paragraph (2).
- (2) The period referred to in paragraph (1) is the period beginning on the date on which the veteran dies and ending on the earliest of the following dates:
 - (A) The date on which the surviving spouse remarries.
- (B) The date on which the surviving spouse gives up an ownership interest in the small business concern.
 - (C) The date that is ten years after the date of the veteran's death.

RESPONSES BY JOE WYNN TO QUESTIONS FROM SENATOR CONRAD BURNS

Question 1. The assumption is often that the presence of venture capital—and the private confidence that it signified—is a good measuring stick for the viability of an idea. Good ideas tend to attract private funding. On the other hand, SBIR was de-

signed to support good ideas that might not be attractive in the marketplace. How do we go about making SBIR as effective at choosing good ideas as possible while maintaining its ability to fund good projects that might not otherwise be developed? Question 2. Should the presence of venture capital factor into the likelihood of re-

ceiving an SBIR award?

Response to Questions 1 and 2. I respectfully decline to offer any response to the above questions 1 and 2 from Senator Bums since I did not include any information in my testimony on SBIR. My testimony was confined to the Service Disabled Veterans Procurement Program and associated activities and/or programs. However, if there is additional time, other members of our Task Force for Veterans Entrepreneurship could share their views on SBIR.

Thank you for allowing me the opportunity to further clarify my views and the views of the many members of the Task Force for Veterans Entrepreneurship on the above referenced issues which are so important to our veterans and veteran busi-

ness owners. I am available for additional comments if needed.

RESPONSES BY STEVEN SIMS TO FOLLOW-UP QUESTIONS FROM SENATOR JOHN F. KERRY

Question 1. What should be done to place ANCs on an equal playing field with other 8 (a) firms?

Answer. The miraculous growth of contract dollars should have raised question some time ago. The leadership responsible should be prosecuted to set an example and so those tribes and individuals not responsible are not unjustly targeted. This solution is one the ANC's not part of this hoax should be recommending. Given the GAO report which speaks to ANC's being used as a past through, and those responsible not even showing the smarts to use other ANC's as subcontractors, so native peoples benefit in some way the punishment should be extreme. The Minority Business Summit Committee (a consortium of MBE business organizations) makes this recommendation reluctantly. ANCs should have their status in the world of 8 (a) be reduced to the same status and competitive entity as other 8 (a) firms.

Question 2. Net worth threshold (NWT) for 8 (a) firms—Does the current NWT prevent legitimate SDB's from participating in the 8 (a) program?

Comment. Before answering, I would like to raise a couple of issues:

1. Because access to capital is so important and difficult for many small firms, particularly minority businesses, it is imperative that they have as strong a cash position as possible. Limiting their net worth appears to be more an impediment to growth than tool certifying the eligibility of small minority businesses to participate in this program.

2. The income limits have neither been adjusted nor modified since the program's inception. This restricts and retards the opportunity for growth, development or suc-

cess on the part of the minority business.

Answer. Yes, the NWT does restrict or prevent legitimate SDBs from participating in the 8 (a) program. I would think that some research and then adjustment to income thresholds based on challenges of the industry and small business size standards would be Senate response useful. At the least, NWT should be tied to inflation over the period since the last adjustment. While not exactly leveling the playing field, it would provide some relief to those in or entering the program.

RESPONSES BY STEVEN SIMS TO FOLLOW-UP QUESTIONS FROM SENATOR CONRAD BURNS

Question 1. Should venture capital factor into receiving an SBIR awards? Answer. I believe venture capital should be factored into the determination of an SBIR award. I do not believe the VC should be a majority owner and still receive the SBIR. My recommendation would be the same as NMSDC has implemented in the private sector for minority businesses needing venture capital to grow. The business must be certified as a small business or small minority owned business. Once certified, the business is allowed to hunt for institutional investors who might be interested in participating in the venture. The business is able to give up equity but not ownership of the venture and must remain in control of the business and must manage the business for it to receive and maintain the SBIR award. A true VC is

interested in return on investment and not management also they come in looking for an exit strategy and thus is betting on the jockey not the horse in the race.

RESPONSES BY DR. CHARLES W. WESSNER TO QUESTIONS FROM SENATOR CONRAD BURNS

Question 1. The assumption is often that the presence of venture capital—and the private confidence that it signified—is a good measuring stick for the viability of a new idea. Good ideas tend to attract private funding.

On the other hand, SBIR was designed to support good ideas that might not be attractive in the marketplace. How do we go about making SBIR as effective at choosing good ideas as possible while maintaining its ability to fund good projects that might not otherwise be developed?

Answer. The question posits that the presence of venture capital is "a good measuring stick" for the viability of an idea. While venture funding is certainly one measure of an idea's viability, it s not necessarily the only good measure. What is more, many venture supported business models do not succeed; hence the tautology that "good ideas tend to attract private funding" may be an overstatement. As the dotcom boom demonstrated, many bad ideas can also attract private investment.

It is also that there are good ideas that do not attract private investment. Nuclear power, GPS, and the Internet are examples of good ideas that certainly did not attract private funding at their origin, or indeed during their long gestation. Private markets are, of course, amazingly effective at exploiting these platform technologies but, historically, this has often been the case only after substantial Federal investments. A virtue of SBIR is that it can help create and signal information about new ideas, and in this way help private venture capital markets work better. The basic point is that Federal investments in research, combined with effective public-private partnerships, such as innovation awards, can help well regulated private markets create new welfare enhancing technologies.

Making SBIR as effective as possible at choosing good ideas has to take into account the diversity of program objectives and agency needs. A virtue of SBIR is that in many respects it can act as a "low cost technological probe," enabling the government to explore ideas that may hold promise. The second phase of the program enables the successful ideas to be developed further. Transitioning to the next phase of development sometimes occurs through the action of private markets, sometimes through procurement. Some government needs can be met by the "answer" provided through the successful conclusion of the phase I or phase II award with no further research required or a product (e.g. an algorithm or software diagnostic). Other awards can provide valuable negative proofs, identifying dead ends before substantial Federal investments are made. And yet other awards require substantial additional funds to meet testing and certification requirements. Recognizing this diversity and the need for flexibility is key to understanding the program and to its effective operation.

Question 2. Should the presence of venture capital factor into the likelihood of receiving an SBIR award?

Answer. The key determinant for receiving an SBIR award should be the quality of the research proposed and its correspondence to agency needs or interests.

As emphasized during the testimony, additional research is needed to determine the number of companies that have received SBIR awards and have venture capital and the outcomes of these awards. This would enable us to have a better understanding of this relationship and therefore what new policies, if any, should be adopted. The absence of such data-driven analysis makes it hard to formulate effective policy on this question.

Watson's Responses to Senator Bond's Questions

Question 1: In your testimony, you refer to the "unlimited venture capital presence" in the SBIR program that you suggest S. 1263 would achieve. Yet does not my legislation limit any since VC to a minority stake in an SBIR company? Doesn't my bill specifically exclude venture capital companies that are controlled by big businesses, such as corporate venture funds? In addition, doesn't my legislation maintain the existing 500-employee limitation as well as the U.S. citizenship test? In fact, I believe my bill is a narrowly tailored approach that allows companies with multiple venture investors to participate in the SBIR - as these companies had for 21 years until the 2003 ruling.

Therefore, my question is this: If you are confident in the scientific merits of your research, why does it appear that you are unwilling to compete on a level playing field against other companies? Do you have reason to believe that NIH awards SBIR grants on anything other than the scientific ment of the grant application?

Answer: When I used the term "unlimited venture capital presence" in my testimony, it was precisely applied. What I was specifically referring to was the fact that, from the very beginning of the SBIR program, participation was "limited" to small businesses in which majority ownership was held by eligible individuals. Businesses majority-owned by venture capital partnerships, have always been ineligible as defined by the SBA size-standards rules. When I used the term "unlimited", I was referring to the fact that, in the event S.1263 becomes law, this limitation will be abandoned.

Yes, S.1263 limits any single VC organization to a minority stake, but as anyone familiar with VC investment practices can tell you, virtually all VC deals are syndicated to minimize risk, thus making this limitation virtually meaningless. The syndicate designates one of the partners to manage the investment, making inoperative the SBA's "independently owned and operated" small business definition. It is not at all clear to me that S.1263 provides an impenetrable firewall preventing some form of corporate venture fund from entering the SBIR competition – corporate attorneys are adept at finding loopholes.

As to maintaining the 500-employee limitation, I have the following observations to make about this pivotal issue. This VC/BIO/SBIR controversy vividly underscores the importance of understanding that the SBA size standard of "500 or fewer employees" is an 'inferential' standard. Having more than 500 employees is not particularly relevant; it is the financial clout that is inferred from having more than 500 employees that is the underlying 'size' issue. A financial organization with a few employees, such as a VC fund, can have far more financial clout than a company with thousands of employees. And, with the now-established practice of VCs forming funding syndicates, the combined financial clout of the syndicate can be huge. This is the fundamental reason VCs should not be allowed to compete with the little guys.

With all due respect, I take strong exception to the claim that VC-backed and VC-owned companies were made SBIR-ineligible by the SBA Office of Hearings and Appeals (OHA) 2003 ruling. This is a widely circulated canard. The fact is — THEY WERE NEVER ELIGIBLE! The OHA upheld and affirmed the size-standards rule that had been in effect from the beginning of the program. There were some VC-owned companies that were illegally participating in the SBIR program and the OHA ruling put a stop to this illicit practice. THOSE ARE THE FACTS!

With regard to the competing on a "level playing field" part. I am at a loss to understand the origin of this question. With all due respect, as those who were there will tell you, the founding and principal purpose of the SBIR program was TO CREATE A LEVEL PLAYING FIELD for small businesses to compete with each other for 2.5% of the Federal R&D budget, while the big guys continued to compete with each other on their own playing field for the other 97.5%. S.1263 will severely tilt the SBIR playing field for the benefit a select group of big guys. The SBIR small business level playing field concept is neither complicated nor irrational, leading one to wonder why it seems to no longer have the traction in the Congress it had 25 years ago. And, yes, I have reason to believe that NIH makes SBIR awards based upon criteria other than scientific merit. The NIH review process is peer review and the reviewers usually know about the company, the researchers, funding, etc. NIH reviews of which I am aware, for example, have noted "the remote location" of the proposing entity – clearly science is not the only factor.

Question 2: You make much of the GAO Report issued in April of this year. Yet, in that report the GAO admitted that it could not distinguish between companies that were majority and minority backed by VC funding. Further, the GAO report only looked at SBIR grants made between 2001 and 2004, yet majority-backed companies were allowed to receive SBIR funds until the ruling in 2003. So the figures you cite about the increase in venture funding and the SBIR program actually includes the majority-venture backed companies that are now ineligible.

Given these facts, to you agree or disagree with the following Small Business Administration quote about the April GAO report: "The data presented in the report has no bearing on program eligibility. For this reason, SBA finds the general discussion of SBIR eligibility to be unclear and potentially misleading." [See letter from SBA Associate Administrator for Government Contracting, Karen Hontz, dated April 2006]

Answer: I don't understand the point about the GAO figures, but, regardless, the figures make my point. Again, with all due respect, the canard of "majority-backed companies" being allowed to receive SBIR funds until the 2003 OHA ruling is repeated – leading one to wonder what motivates this total disregard of the facts. I am unfamiliar with the Hontz letter and have no opinion on it.

Question 3: How capital intensive is your business? Do you have revenue from products you are selling? Does your product have to go through anything like the 3-stage Food and Drug Administration approval process that drug development firms face?

Would you say that the economics of your product development are fundamentally different from the economics of drug and medical device development, which can cost hundreds of millions of dollars and take a decade or more? Viewed in this light, isn't a reliance on venture funds understandable in the drug development world, if not in your line of business?

Answer: This is one of those "I'm glad you asked that" questions because it makes my point, maybe far better than I have done. The answer is that the small businesses the SBIR program was designed to serve were never intended to receive funding to cover the FDA approval process that "...can cost hundreds of millions of dollars and take a decade or more...". It is nonsensical to expect the SBIR program to make a dent in meeting funding requirements of this magnitude – the entire NIH annual SBIR budget is of the order of \$700 million.

Companies that require large capital investments should go to large capital sources (such as VC funds) and not undermine the SBIR program which is designed for embryo companies with modest seed capital requirements. If federal funding is necessary for the development of biotechnology, a program should be developed specifically for that purpose, and funding should come from the 97.5% of the federal extra-mural R&D budget that is not set-aside for SBIR. Even if the entire \$700 million NIH SBIR budget was earmarked exclusively for biotech R&D, it is a drop in the bucket compared to the needs of this huge enterprise - estimated total public & private expenditures approach \$100 billion annually. There will never be enough funding for human health needs - no matter how much is spent, there will always be demand for more. Why destroy a 25 year-old \$2 billion program that really works in an attempt to satisfy this insatiable demand, especially when the beneficiaries are venture capital organizations with hundreds of billions to invest? Trying to meet the capital needs of VC-owned biotech companies using SBIR resources is a lose/lose strategy destroying the SBIR program while having virtually no effect in addressing the needs of the VC-owned biotech client. The root cause of this controversy is the perceived lack of funding programs at the NIH for companies that are not SBAdefined small businesses. One solution would be for Congress to mandate that the NIH expand its "Phased Innovation" programs which are essentially SBIR-like programs for large institutions (both for-profit and not-for-profit). This would be the best way to address the drug development problem that Senator Bond described at the hearing, since many times more funding would be available than SBIR offers.

Watson's Responses to Senator Burns' Questions

Question 1: The assumption is often that the presence of venture capital – and the private confidence that it signified – is a good measuring stick for the viability of an idea. Good ideas tend to attract private funding. On the other hand, SBIR was designed to support good ideas that might not be attractive in the marketplace. How do we go about making SBIR as effective at choosing good ideas as possible while maintaining its ability to fund good projects that might not otherwise be developed?

Answer: Good Question. Venture capital favors low risk, high, quick reward opportunities, just as it should – that's what their investors demand, and there are enough deals of this nature (concentrated in a few states) to keep them busy. SBIR seed capital is most valuable when it goes where VCs fear to tread; risky but needed innovations with low, slow payout potential. It is the only organized source of seed capital for these ventures in much of the country. Your question bears on how one can determine the right balance between these conflicting priorities. I don't have a good answer and don't think one is needed. The SBIR program as it was originally conceived has existed for the past nearly 25 years and is widely acknowledged to be highly successful in generating start-up companies nationwide, particularly in those regions where VCs won't go. This unparalleled record of success strongly recommends that the program continue unaltered. That's why I paraphrase that country phrase with - "SBIR ain't broke, don't break it".

Question 2: Should the presence of venture capital factor into the likelihood of receiving an SBIR award?

Answer: No, it should not and as evidence in support of this position, I reference an article authored by two venture capitalists titled "How Venture Capital Thwarts Innovation" (IEEE SPECTRUM, April 2005). They found that the level of innovation in the 1990's did not correlate well with VC funding. They ascribed this "dismaying" lack of venture capital sponsorship of innovation to a number of factors, chief among them being the well-known VC aversion to risk. The VC's 'value proposition' to their investors is "minimize risk, maximize return", and, as an investor, one would expect no less. VC investing "...is all too often a mechanical process of reviewing business-school checklists". Few VCs really understand fundamental research and those that do usually don't really understand business. So, the conclusion is that VCs are no more skilled at assessing innovative merit and likelihood of success than other well-informed and involved individuals. SBIR is the nation's most accessible source of seed capital for risky innovative start-ups – the kind of enterprise this nation excels at generating – and the kind of ventures VCs avoid.

This VC/BIO/SBIR controversy vividly underscores the importance of understanding that the SBA size standard of "500 or fewer employees" is an 'inferential' standard. Having more than 500 employees is not particularly relevant; it is the financial clout that is Inferred from having more than 500 employees that is the underlying 'size' issue. A financial organization with a few employees, such as a VC fund, can have far more financial clout than a company with thousands of employees. And, with the now-established practice of VCs jointly funding a venture, the combined financial clout of the syndicate can be huge. This is the fundamental reason VCs should not be allowed to compete with the little guys.

EW - 7/24/06

Watson's Responses to Senator Enzi's Questions

Question 1: Do Wyoming companies participate in the NIH portion of the SBIR program?

Answer: Yes, but not recently. The NIH has made 21 Phase I and 7 Phase II awards to Wyoming small businesses over the past 10 years – but only one award has been received over the most recent 2.5 years. This is a disaster for Wyoming's emerging bio-tech start-ups; for example, DeltaNu would not be able to get established under the current circumstances.

<u>Follow-up Question:</u> You testified that increased VC participation in the SBIR program would crowd out rural participation in the SBIR program. Is there any evidence of this in Wyoming?

Answer: Yes, there is persuasive evidence. The recent GAO report reveals that at NIH, VC companies are taking a growing share of the total NIH SBIR budget, up from 14% in FY01/02 to 21% in FY03/04. And firms having venture capital investment tend to receive the largest awards Since SBIR is a zero sum game, it is obvious, then, that companies without VC investment are losing share. With 85% of VC funds being invested in 10 states, it necessarily follows that small businesses in the other 40 states are the losers, Wyoming included.

Over the 7 years '97-'03, Wyoming averaged 4 NIH awards per year - but has received only one NIH award in the 2.5 years since 2003. The GAO report states that 70% of the NIH SBIR budget now goes into awards exceeding the guideline caps. With the larger awards going to VC companies (larger awards = fewer awards) then obviously the little guys in the 40 VC-underserved states are being crowded out. One \$500,000 Phase I award crowds out four little guys - one \$5,000,000 Phase II award crowds out seven little guys. It has been said that when the NIH SBIR budget doubled, the number of awards rose by only 20%.

<u>Question 2:</u> In your opinion, what are some legislative options for the Committee that would maintain the integrity of the SBIR program as a small business program, but still acknowledge the unique needs of small businesses that seek venture capital for high-capital industries, such as biotechnology?

Answer: Companies that require large capital investments should go to large capital sources (such as VC funds) and not undermine the SBIR program which is designed for embryo companies with modest seed capital requirements. If federal funding is necessary for the development of biotechnology, a program should be developed specifically for that purpose, and funding should come from

the 97.5% of the federal extra-mural R&D budget that is not set-aside for SBIR. Even if the entire \$700 million NIH SBIR budget was earmarked exclusively for biotech R&D, it is a drop in the bucket compared to the needs of this huge enterprise – estimated total public & private expenditures approach \$100 billion annually. There will never be enough funding for human health needs – no matter how much is spent, there will always be demand for more. Why destroy a 25 year-old \$2 billion program that really works in an attempt to satisfy this insatiable demand, especially when the beneficiaries are venture capital organizations with hundreds of billions to invest? Trying to meet the capital needs of VC-owned biotech companies using SBIR resources is a lose/lose strategy – destroying the SBIR program while having virtually no effect in addressing the needs of the VC-owned biotech client.

The root cause of this controversy is the perceived lack of funding programs at the NIH for companies that are not SBA-defined small businesses. One solution would be for Congress to mandate that the NIH expand its "Phased Innovation" programs which are essentially SBIR-like programs for large institutions (both forprofit and not-for-profit). This would be the best way to address the drug development problem that Senator Bond described at the hearing, since many times more funding would be available than SBIR offers.

Question 3: I notice in your testimony that you had some other recommendations for the SBIR program. What are they?

Answer:

- 1. Adjust the Phase I & Phase II award guidelines (to at least \$150,000 and \$1,250,000) to account for 15 years of inflation.
- 2. Require the agencies to adhere to the award guidelines. Larger awards means fewer awards; fewer awards means fewer little guys, especially those from rural areas.
- 3. Increase the set-aside from 2.5% to 5% (0.5% per year for five years).
- 4. Allow the agencies to cover program administrative costs out of their SBIR budgets (with a % cap). I am convinced that the administrative burden imposed as a result of the five-year doubling of the NIH budget forced the NIH administrators to institute the practice of making "jumbo" awards, leading to the strong VC interest in the NIH SBIR program, resulting in the crowding out of the little guys. IMHO, this unintended consequence would have been avoided if the NIH SBIR administrative budget had kept pace with the rapidly increasing work load.

5. Speed up the proposal evaluation and award process – it is paced for bureaucrats, not entrepreneurs (it can take as long as eight months at some agencies). Require each agency to have at least two proposal submission cycles per year. Require that the evaluation/award process be completed in 120 days. This should be achievable, especially if the agencies are allowed access to a percentage of their total SBIR funds to cover administrative costs.

Follow-up Question: Which of these recommendations is most important?

Answer: My most urgent recommendation is to continue to reserve the SBIR program solely for small businesses that are "Independently owned and operated" – "It ain't broke, don't break it". Do not compromise the existing SBA size standards to allow large financial organizations to force out the little guy. The SBIR program was specifically created to provide entry for the little guy into a small fraction of the Federal R&D funding arena. The VC big guys should compete with the other big guys for the remaining 97.5% of the Federal extramural R&D budget.

This VC/BIO/SBIR controversy vividly underscores the importance of understanding that the SBA size standard of "500 or fewer employees" is an 'inferential' standard. Having more than 500 employees is not particularly relevant; it is the financial clout that is inferred from having more than 500 employees that is the underlying 'size' Issue. A financial organization with a few employees, such as a VC fund, can have far more financial clout than a company with thousands of employees. And, with the now-established practice of VCs jointly funding a venture, the combined financial clout of the syndicate can be huge. This is the fundamental reason VCs should not be allowed to compete with the little guys.

EW 7/24/06

RESPONSES BY DR. MICHAEL SQUILLANTE TO QUESTIONS FROM SENATOR CHRISTOPHER S. BOND

Question 1. In your testimony, you refer to the "unlimited venture capital presence" in the SBIR program that you suggest S. 1263 would achieve. Yet does not my legislation limit any since venture capital to a minority stake in an SBIR company? Doesn't my bill specifically exclude venture capital companies that are controlled by big businesses, such as corporate venture funds? In addition, doesn't my legislation maintain the existing 500-employee limitation as well as the U.S. citizenship test? In fact, I believe my bill is a narrowly tailored approach that allows companies with multiple venture investors to participate in the SBIR—as these companies had for 21 years until the 2003 ruling.

Therefore, my question is this: If you are confident in the scientific merits of your research, why does it appear that you are unwilling to compete on a level playing field against other companies? Do you have reason to believe that NIH awards SBIR

grants on anything other than the scientific merit of the grant application?

Answer. I appreciate the opportunity to testify before the Small Business and Entrepreneurship Committee and the further opportunity to provide additional information. We are all after the same goal: improving the SBIR Program.

My concerns are that the proposed changes will alter the SBIR program, shifting its focus toward development and clinical studies and away from innovative received and existing breakthroughs. I am also convinced that the change will result search and scientific breakthroughs. I am also convinced that the change will result in many fewer, much larger NIH awards. This will make it very much harder for small companies that do not have access to other funding to receive SBIR grants. Thus, a change in the Affiliation Rule will precipitate a paradigm change in Small Business early stage support, thereby impacting the national economy by discourage the start-up and growth of small businesses that are demonstrated to be one of the most effective means of creating new jobs. Given the large contribution that small businesses are making to the nation's economy, a major change in the Affiliation Rule will have a negative impact on the economy over the long term.

I have divided your first question into its several parts:

First, as written S. 1263 very specifically does not limit venture capital firms and the small companies they control to 500 employees plus affiliates. Never, in the entire history of SBIR, have any firms with more than 500 employees including affiliates been legally allowed to participate, whether venture capital funded or not. S. 1263 would, for the first time, waive this critical affiliation rule. This is my most serious concern to S. 1263.

One thing is very clear; a change in the Affiliation rules that permits large venture capitalists to take advantage of the SBIR Program for clinical trials and product development will unleash major paradigm shift in the means available for techbased small businesses to get support for new innovative technology and R&D projects. As the pathways for small businesses are whittled down until the passageway is too narrow and unattractive, we will have effectively choked off one of the best engines for economic growth that the nation has going for it.

If the intent of S. 1263 is truly to preserve the 500 limit, why does it specifically

waive the affiliation rule for venture capital firms? Why only for venture capital companies, why not for other ownership?

Second, in addition, some proponents of S. 1263 have publicly stated that they are not satisfied with \$100,000 Phase I program and \$750,000 Phase II programs. They state they need \$1,000,000 in Phase I and \$10,000,000 in Phase II. This will reduce the number of SBIR award by a factor of 10 to 12. If awards like this are routinely made, the odds of wining will plummet and it will drive 90% of small, high tech companies out of SBIR. SBIR will very quickly become the venture capital Supple-

mental Development Insurance Fund.

Would you be willing to support a firm, absolute cap on the size of awards? Possibly the limit could be one and one half to two times the limit recommended in the legislation? For example, the present limit is \$750,000 and the cap would be \$1,125,000 to \$1,500,000. If the limit is raised in the reauthorization to \$1,000,000 then the cap would be \$1,500,000 to \$2,000,000. These would still be huge awards, but they would not cripple SBIR.

Third, also, allow me, respectfully, to point out that if venture capital controlled firms participated in SBIR prior to 2003, they did so illegally. Venture capital controlled firms were never lawfully permitted to participate in SBIR. They did so prior to the ruling either because they did not provide the proper certifications (which viototic property). lates the law) or agency administrators ignored the ownership of the firms either through laziness or negligence.

Fourth, related to the question of multiple venture capital ownership, the question is not whether a venture capital firm owns less that 49%, it is whether or not the

"individual" owns more than 50%. It is not clear how multiple venture capital ownership affects the question. However, I assume that no one would allow a company controlled by a foreign venture capital firm to participate. In the event that a company was controlled by multiple venture capital owners, and some of the them are foreign, how much SBIR funding should go to benefit foreign investors?

Fifth, I am willing to compete with any companies "on a level playing field", that is as long as the same rules apply to me and to those I compete with. Section 3 of S. 1263 provides a special waiver to the affiliation rule only to venture capital funded companies. They would have a significant advantage over real small companies that do not have access to the capital and equipment that the venture capital firms provide. Do the venture capital firms need special rules that only apply to them in order to compete?

SBIR is an intensively competitive program. Less than 1 out of 10 NIH SBIR Phase I applications are funded. Increased participation by large venture capital firms will dramatically reduce this to 1 in 20 or fewer.

Question 2. You make much of the GAO Report issued in April of this year. Yet, in that report the GAO admitted that it could not distinguish between companies that were majority and minority backed by venture capital funding. Further, the GAO report only looked at SBIR grants made between 2001 and 2004, yet majoritybacked companies were allowed to receive SBIR funds until the ruling in 2003. So the figures you cite about the increase in venture funding and the SBIR program actually includes the majority-venture backed companies that are now ineligible.

Given these facts, to you agree or disagree with the following Small Business Administration quote about the April GAO report: "The data presented in the report has no bearing on program eligibility. For this reason, SBA finds the general discussion of SBIR eligibility to be unclear and potentially misleading." [See letter from SBA Associate Administrator for Government Contracting, Karen Hontz, dated

April 2006]

Answer. First, the statement has been made by advocates of S. 1263 that venture capital backed firms can no longer compete in NIH SBIR. I cited the GAO report because it clearly refutes this statement. The fact is that venture capital companies are participating at higher levels than ever before and that participation is increasing rapidly.

Second, firms that were majority owned by venture capital firms were never legally allowed to participate in SBIR.

Third, I believe that eligibility, as it applies to affiliation, is very clear and should apply equally to all participants.

Question 3. How capital intensive is your business? Do you have revenue from products you are selling? Does your product have to go through anything like the 3-stage Food and Drug Administration approval process that drug development firms face?

Would you say that the economics of your product development are fundamentally different from the economics of drug and medical device development, which can cost hundreds of millions of dollars and take a decade or more? Viewed in this light, isn't a reliance on venture funds understandable in the drug development world, if not in your line of business?

Answer. I spoke at the hearing representing the Small Business Technology Council of the NSBA. Obviously this organization does not have products. The company I work for does sell products and, yes, some are medical products that require FDA approval. Thus, I do understand why venture capital funding is used to support pharmaceutical development. I also believe that this work is important and nec-

essary and I know that the studies are long and expensive.

The studies, however, are not "innovation research" and, as such, do not properly belong in the SBIR program. SBIR is supposed to fund innovations before they have reached the state of development where they can attract venture capital funding.

This is not a problem faced only by venture capital funded firms. I have had several NIH SBIR applications rejected because the NIH reviewers felt that the technology was too advanced and no longer innovative. Just last year I submitted a proposal that was not funded. The reviewers found that "The PI (Principal Investigator) is one of the leaders in the field" and "This is important research and the work could have a positive impact." However, they also noted: "These studies are not very innovative" and "nothing revolutionary has been proposed." Obviously, this hurts, but it is the key criterion for funding SBIR research.

I definitely believe that the NIH should have a program that supports clinical studies for drug development. This should not come out of the small 2.5% SBIR pro-

gram. When SBIR is reauthorized, it would be a wonderful idea to have an additional allotment of funding, possibly 1% of the NIH extramural budget, to fund clin-

ical studies related to technologies developed under SBIR. I would gladly work with you and the committee to develop a concept like this.

RESPONSES BY DR. MICHAEL SQUILLANTE TO QUESTIONS FROM SENATOR CONRAD BURNS

Question 1. The assumption is often that the presence of venture capital—and the private confidence that it signified—is a good measuring stick for the viability of an idea. Good ideas tend to attract private funding. On the other hand, SBIR was designed to support good ideas that might not be attractive in the marketplace. How do we go about making SBIR as effective at choosing good ideas as possible while maintaining its ability to fund good projects that might not otherwise be developed?

Answer. I believe that venture capital funding does indeed give credence that an idea has huge commercial potential. It does not, however, mean that an idea has merit and can solve important medical problems. (This is obvious by the enormous resources that go into clinical studies for cosmetics.) If this were the only criterion for performing SBIR research, many diseases would not be investigated and many problems would never be solved.

A very specific example is the research we carried out under an NIH SBIR program that led to an order of magnitude decrease in the incidence of stroke during open-heart surgery and has changed the way open-heart surgery is performed in hospitals throughout the United States. If commercial potential and venture capital involvement were important criteria, this would not have been funded and the incidence of stroke following open-heart surgery would be 10 times higher than it is today.

In addition, the development of new technologies for medical research would come nearly to a standstill. SBIR is the primary mechanism today for technology development in medical research in the United States. For the most part, investigations into new tools for medical researchers would not get done. Large companies are not doing it, and venture capital firms obviously would not fund it.

Question 2. Should the presence of venture capital factor into the likelihood of receiving an SBIR award?

Answer. All SBIR proposals should be judged on their technical merit and the potential impact of the research.

The issue of venture capital should be a factor relative to the size of the company and the total number of all of its affiliates.

RESPONSES BY THOMAS J. BIGGER TO QUESTIONS FROM SENATOR CHRISTOPHER S. BOND

Question 1. The text for question 1 was not available at press time.

Answer. Biotechnology and medical device companies are disproportionately impacted by the new SBIR eligibility rules because these industries rely upon venture capital investments to fund research and development over long time horizons. By some accounts, it can take 10-15 years and \$800 million to develop a new biotech product. During this time, a small biotech firm will likely have no revenue from product sales. Hence, biotech companies are heavily dependent on venture capital backing, even at very early stages of product development.

Question 2. [The text for question 2 was not available at press time.] Answer. Paratek has 66 employees. We are typical of the numerous biotechnology companies with fewer than 100 employees who find themselves majority venture capital backed due to the very capital intensive nature of biotech research and development. Like the vast majority of the biotech industry today, we are a small com-

Question 3. [The text for question 3 was not available at press time.]

Answer. We maintain day to day management of the company. Our firm is run by our management team, not by our venture capital investors. In general, venture capitalists are looking to invest in technologies that are promising. They are not looking to run their portfolio companies. In the case of Paratek, no single venture firm owns more than 5 percent of the company's stock

Question 4. [The text for question 4 was not available at press time.]

Answer. We hear anecdotal evidence that promising research is being turned away by NIH due to the new eligibility interpretation. NIH has stated that the rules prohibit funding of research with the potential to improve human health, research that NIH would like to fund but cannot. According to a survey by the Biotechnology Industry Organization, roughly half of biotech companies with majority venture capital backing had cancelled or delayed a project due to the new SBIR rules.

Question 5. [The text for question 5 was not available at press time.]

Answer. The simple answer is that venture capital funding often goes to product development that is further along while SBIR dollars help to fund the earliest stage research. The SBIR eligibility rules, however, are not product specific, but instead look at the capital structure of the company. So a company that has become majority VC-backed by virtue of funding for one product is no longer eligible for SBIR funds for different products at earlier stages of development.

Question 6. [The text for question 6 was not available at press time.]

Answer. In our case, we had to actually lay off employees due to the funding restriction. Under the new eligibility interpretation, not only is the public losing out on the benefits of research that could provide new therapies, but in some cases there is a direct negative economic impact to the community as well.

RESPONSES BY THOMAS J. BIGGER TO QUESTIONS FROM SENATOR CONRAD BURNS

Question 1. [The text for question 1 was not available at press time.]

Answer. My view would be to allow the agencies, NIH for example, to make the decisions as to what research gets funded. The eligibility rules should not screen out companies based upon whether or not they have raised private capital. The eligibility rules should be as neutral as possible so as to allow all small companies to compete. We should have confidence in the peer review process implemented by the agencies that participate in the SBIR program. Put simply, Congress should do what it can to ensure that SBIR funding decisions are made, to the extent possible, based upon the merit of the scientific research at issue.

Question 2. [The text for question 2 was not available at press time.]

Answer. The legislative history and statutory language of the bill creating the SBIR program indicates that Congress viewed the presence of private investment as a positive factor in the decision making process regarding Phase II SBIR awards. This represents a recognition by Congress that ideas that attract private funding are more likely to succeed. Viewed from this perspective, SBIR funds are more likely to result in commercialization of a new product where the ability of the firm to attract private capital is taken into account.

Having said that, however, there are many worthwhile projects that could benefit from SBIR funds that have not attracted private investment. In our industry, in particular, a company may raise private funding for a specific product and may then apply for SBIR funding for different products that are too early stage to raise private funding. Whether the SBIR program should contemplate the fact that a company, or a specific product, has raised venture capital or other private investment funds is a policy decision that Congress will ultimately have to make.

RESPONSES BY THOMAS J. BIGGER TO QUESTIONS FROM SENATOR MICHAEL B. ENZI

Question 1. [The text for question 1 was not available at press time.]

Answer. This is a problem specific to companies that have long product development cycles in heavily capital-intensive fields of research. Biotech companies are a prime example of this situation, as are medical device companies.

Question \dot{z} . [The text for question 2 was not available at press time.]

Answer. NIH has been the agency most impacted by the new SBIR eligibility rules. However, other government SBIR participants, such as the Department of Defense, may want the ability to fund promising research and development by companies that are venture backed. Rather than making the solution NIH-specific, a preferable alternative would be to grant participating agencies the discretion to make awards to majority-backed firms where doing so would advance the mission of the agency's SBIR program.

COMMENTS FOR THE RECORD

Madam Chairwoman, Senator Kerry, Members of the Committee:

Thank you for inviting me to testify regarding the work of the Acquisition Advisory Panel ("Panel"). With the Committee's permission, I will speak briefly about the Panel and its mission. I will then discuss the role of the Small Business Working Group within the Panel. Next, I will describe the Panel's deliberative process. I will conclude with a brief description of some of the Working Group's preliminary findings and recommendations.

About the Panel:

In response to Section 1423 of The Services Acquisition Reform Act of 2003 ("SARA"), the Office of Management and Budget established the Panel in February, 2005, and charged it with reviewing all laws, regulations, and government policies focusing upon four specific areas of the Government's services acquisition process. Those areas are: the use of commercial practices; performance-based contracting; the performance of acquisition functions across agency lines of responsibility; and the use of Governmentwide contracts.

OMB appointed 14 members with recognized expertise in acquisition law and Government acquisition policy, including individuals from government, private industry and academia. The Panel has been supported by staff from the General Services Administration. I should note here that this Panel does not have budget or staff resources of the type provided to the 800 Panel. At the moment, we have 1.5 full time staff members. GSA has made two other individuals available part time to assist the Panel. So, the work of this Panel is being done by its members – in addition to their regular jobs.

The Panel is a Federal Advisory Commission and subject to the Federal Advisory Commission Act ("FACA") and other public disclosure statutes. As a result, we have made every effort to hold regular full Panel meetings in public so that the progress of the Working Groups on the various issues and the views of Panel members on those issues would be available. Between February 2005 and today, the Panel has held 22 Public Meetings. We have at least four additional meetings planned before the end of August. The Panel has heard testimony from 102 public witnesses and 88 appearances on behalf of organizations or groups. The Panel has heard testimony from representatives of ten small businesses, sixteen large commercial entities, four government oversight offices, 30 government organizations, ten associations, one government watchdog organization, and five academic organizations. In all, we have recorded more than 5,500 pages of transcripts from the public meetings.

The Panel's findings were initially due in February of this year. The National Defense Authorization Act of 2006 extended the Panel through August. We expect to present a report to the Office of Federal Procurement Policy and to the Congress this Fall.

About the Small Business Working Group:

Although services acquisition rules affecting small businesses were not among the four specifically enumerated Panel areas of focus listed in SARA, we recognized early the importance

of small business and the potential that findings and recommendations in the four areas above could affect small businesses. As this Committee knows well, small businesses play important roles in providing services to the Government, and there are many laws, regulations and government policies governing small businesses' role across the acquisition process.

We created a cross-cutting Small Business Working Group, chaired initially by Melanie Sabelhaus, Deputy Administrator of the Small Business Administration, and later by David Javdan, the General Counsel of the Small Business Administration. This Working Group was tasked with reviewing the regulatory structure affecting small business service contracting efforts across all four specifically enumerated areas of Panel focus. The other members of the Working Group are Louis Addeo, President of AT&T Government Solutions; Deidre Lee, currently Deputy Director of Operations for the Federal Emergency Management Agency; and, Roger Waldron, Acting Senior Procurement Executive, General Services Administration.

The members of the Working Group have contributed their time, energy and expertise to this Working Group as well as other Panel Working Groups on which they serve. These individuals have spent significant time and energy conducting research, hearing testimony across the country, in meeting to consider findings, and drafting preliminary findings and recommendations.

About the Panel's Deliberative Process:

The Panel's first objective was to gather as much background information relevant to our Charter as possible. The Panel reviewed relevant laws, regulations and policies, and heard extensive testimony. Panel Working Groups then reviewed the information, asked clarifying questions of witnesses, and deliberated at length before issuing preliminary findings and recommendations for consideration by the Panel as a whole. As the Small Business Working Group (and the other groups) have developed preliminary analyses, findings and recommendations, those have been presented to the full Panel and to the Public. The Panel's process is deliberative – the findings and recommendations are the result of discussion, debate, and resolution of differing points of view.

Small Business Working Group's Preliminary Findings:

Of particular interest to this Committee are the results of the Small Business Working Group's deliberations. The preliminary findings and recommendations to date focus on six areas: clarifying preference program use; affording contracting officers discretion to meet agency goals; improving small business access to multiple award contracts; deploying training and best practices on un-bundling contracts; precluding cascading procurements; and, increasing awareness of agency officials on the requirements and benefits of small business contracting. Slides covering the Small Business Working Group's preliminary findings and recommendations are attached as Appendix A. These findings and recommendations were adopted provisionally by the full Panel following discussion and debate during meetings on January 31, 2006 and February 23, 2006. I ask the Committee to take note that the findings and recommendations may change or continue to evolve because the Panel has not yet finished its deliberations in other areas. It is possible other portions of the Panel's work may affect the first set of provisional small business findings and recommendations.

Guidance On Priority for Applying Small Business Contracting Preferences

The Working Group heard testimony from numerous government agencies and contractors concerning contracting officers' understanding of small business contracting preferences. The Working Group also reviewed laws, regulations and policies in place concerning small business preferences and found numerous overlapping – and at times contradictory – pronouncements. For example, The Small Business Act sets forth several specific contracting or business assistance programs, which include the 8(a) Business Development, HUBZone, Small Disadvantaged Veteran Owned Business, and Woman Owned Small Business programs. While the Small Business Administration has attempted to reconcile the Small Business Act's various programs in its regulations², the Federal Acquisition Regulation offers a different interpretation in some instances. For example, on one hand, the SBA regulations stating contracting officers should consider setting aside the requirements for 8(a), HUBZone, or veteran owned businesses before considering setting aside the requirement as a small business set-aside. On the other hand, the FAR provides that before deciding to set aside an acquisition for small businesses, HUBZone or veteran owned businesses, the contracting officer should review the acquisition for offering under the 8(a) Program.

As a result of the testimony and additional research into small business contracting regulations, the Working Group issued a preliminary finding that contracting officers need definitive guidance on the priority for applying the various small business contracting preferences to particular acquisitions. The Working Group recommended amending the Small Business Act to resolve the apparent confusion regarding the mandatory and discretionary nature of the small business contracting programs.

Contracting Officer Discretion in Selecting Small Business Contracting Methods

As a consequence of the misaligned state of statutes and regulations, the Working Group found that contracting officers would benefit from explicit guidance on how to exercise their discretion in selecting the appropriate small business contracting method for a procurement. The Working Group recommended providing guidance clarifying that contracting officer discretion in selecting small business contracting methods should be based on small business goal achievements and market research. This approach provides more flexibility to the buying agencies in meeting their small business goals.

¹ See 15 U.S.C. § 637(a), § 637(a)(1)(D), § 637(a)(1)(B) for 8(a) program statutory preferences; 15 U.S.C. § 657a(B)(2) for HUBZone program statutory preference; 15 U.S.C. § 657f(a), §657(B) for veteran owned business statutory preferences; and, 15 U.S.C. § 637(m) for woman owned business statutory preferences.

² See 13 C.F.R. § 124 for 8(a) program preferences promulgated in the regulations; 13 C.F.R. § 124 for small disadvantaged business preferences promulgated in the regulations; 13 C.F.R. § 126 for HUBZone business preferences promulgated in the regulations; and, 13 C.F.R. § 125 for veteran owned business preferences promulgated in the regulations. The SBA has not yet issued regulations implementing the woman owned small business program.

³ 48 C.F.R. § 19.1305(b), § 19.502-2(b), § 19.1405(a). ⁴ 13 C.F.R. §§ 124.503(j), 125.19(b) & 126.607(b).

^{5 48} C.F. R. § 19.800(e).

Cascading Procurements

The Panel heard sometimes emotional testimony from a number of small business owners concerning the impact of shifting preferences during public meetings in Washington, D.C., Texas, and California. It became clear that owners of small disadvantaged businesses did not understand the preference statutes, regulations and policies.

The Working Group learned agencies are confused as well. In an attempt to quickly and efficiently administer a contract, some agencies are using so-called "cascading" procurements. In other words, the agency will issue a solicitation that is open to 8(a), HUBZone, Veteranowned small businesses, and other small businesses, and list in the solicitation a cascading order of priority according to entity type. The Working Group found that, while not specifically precluded by statute, no statute or regulation provides guidance on the use of cascading procurement. This has led to issues with implementing cascading procurements.

The Working Group has put forth a finding that cascading procurements fail to balance the Government's interest in quick contracting with the requirement for the maximum practicable small business contracting opportunities. The associated recommendation is to amend governing statutes and regulations to expressly preclude cascading procurements as an acquisition strategy.

I should note that, while the 2006 National Defense Authorization Act contained language prohibiting cascading procurements in a number of situations, the Working Group and Panel concluded the language did not go far enough. The Working Group and the Panel could not locate any reasonable justification for permitting cascading procurements, even in limited circumstances.

Bundling

The Panel also heard testimony concerning the effects of contract bundling, and the perception among a number of small disadvantaged business owners that, despite the increase in Federal purchasing, contract consolidation has resulted in a decline in contract awards to SBCs. As the Committee is aware, the Small Business Act allows an agency to bundle its requirements if the agency has performed sufficient market research and has justified the bundled action. The Act also requires agencies to preserve small business prime and subcontract participation to the maximum extent practicable. Reports from the Office of Federal Procurement Policy and the SBA's Office of Advocacy show that, indeed, the use of consolidated contracts has resulted in a decline of awards to SBCs. In 2002, President Bush announced an anti-bundling plan to address

⁶ Office of Federal Procurement Policy, <u>Contract Bundling: A Strategy for Increasing Federal Contracting Opportunities for Small Businesses</u>, at 3-4 (Oct. 2002), <u>citing to Office of Advocacy</u>, U.S. Small Bus. Admin., <u>The Impact of Contract Bundling on Small Business FY 1992-FY 2001</u>, at 5 (Oct. 2002).

the decline. Since then, however, GAO and SBA Inspector General reports show that many agencies are not complying with anti-bundling efforts.

The Working Group issued a preliminary finding that the contracting community does not properly apply and follow the governing contract bundling definition and requirements in planning acquisitions. The Working Group recommended providing additional training and create an interagency group to develop best practices and strategies to unbundle contracts and mitigate the effects of contract bundling. [Panel adopted this approach provisionally.]

Training for Agency Officials

An overarching theme in the testimony before the Panel is the conflict between the desire for rapid contract award and the important social and economic goals of the small business preference programs. The Working Group found agency officials need targeted training to better acquaint them with the requirements, opportunities, and benefits of contracting with small businesses. The Working Group recommended OFPP coordinate the development of a government-wide training module on small business contracting and subcontracting with small businesses.

Reserving Prime Contract Awards for Small Businesses in Multiple Award Procurements

The Working Group examined the effects of multiple award contracts on small businesses' ability to compete for prime and subcontracts. The passage of the Federal Acquisition Streamlining Act of 1994⁸, the enactment of the Clinger-Cohen Act⁹, and the expansion of GSA's Multiple Award Schedules program had led to a marked increase in the use of multiple award indefinite delivery, indefinite quantity ("IDIQ") vehicles to place orders. 10 The Working Group examined data suggesting small businesses have been able to compete for and obtain multiple award IDIQ contracts and subcontract orders. 11 This appears to be due in large part to innovative procurement procedures employed by procuring agencies to meet their annual small business prime contracting goals. Some procuring agencies have "reserved" one or more prime contract awards for small businesses under solicitations that were competed as full and open. Others have awarded IDIQ contracts that contain ordering procedures that limit competition for an order to small businesses. However, is unclear whether agencies have the authority for these actions and not all agencies are willing to take these steps.

The Working Group found the strategy of reserving prime contract awards for small businesses in full and open multiple award procurements may be effective in providing small business prime contracting opportunities. As such, the Working Group recommended providing authorization

⁷ See Gen. Acct. Off., Rep. No. GAO-04-454, Government Accountability Office, Contract Management: Impact of Strategy to Mitigate Effects of Contract Bundling on Small Business is Uncertain (2004); U.S. Small Bus. Admin. Inspector General, Audit Rep. No. 5-20, Audit of the Contract Bundling Process (2005).

Pub. L. No. 103-355, 108 Stat. 3423 (1994).

⁹ Divisions D and E of the National Defense Authorization Act for Fiscal Year 1996 (Pub. L. No. 104-106, 110 Stat. 186 (1996)).

¹⁰ See Gen. Acct. Off., Rep. No. GAO-04-738T, Small Business: Trends in Federal Procurement in the 1990s, pp.

^{12-20 (2001)}See id.; Gen. Acct. Off., Rep. No. GAO/NSIAD-98-215, Acquisition Reform: Multiple-Award Contracting at Six Federal Organizations,

for small business reservations of prime contract awards in full and open multiple award procurements that are not suitable for competition exclusively by small businesses. [Panel adopted this approach provisionally.]

The Working Group also found the contracting community needs explicit guidance on utilizing small business reservations for orders against multiple award IDIQ contracts. To that end, the Working Group recommended providing a statutory and regulatory amendment granting agencies explicit discretion to limit competition for orders to small businesses. [Panel adopted this approach provisionally.]

Conclusion:

In closing, I would like to note that the Panel is continuing to evaluate the findings and recommendations of its other Working Groups with an eye toward the impact on small business. There are other proposals under consideration – of course it remains to be seen whether we can achieve agreement on those proposals. We look forward to presenting our full report this Fall.

It has been an honor to appear before the Committee. I would be happy to answer any questions you may have.

Acquisition Advisory Panel

Small Business Working Group Cross-Cutting Issues:

Revisions to

Preliminary Draft Recommendations February 23, 2006

These slides contain preliminary working group findings and recommendations for discussion purposes only. They have not been approved by the Acquisition Advisory Panel

Summary of Proposed Revisions

- Clarify guidance on the order of priority in utilizing small business contracting methods
- Add a previously omitted recommendation concerning cascading procurements
- Revise the proposed amendments authorizing reservations of small business prime contract awards in full and open multiple award
- Clarify the justification for the recommendation concerning the limitations on subcontracting

Contracting officers need definitive guidance on the priority for applying the various small business contracting preferences to particular acquisitions

Recommendation #1

Amend the Small Business Act to provide consistent statutory language governing the applicability of the various small business preference programs

[Recommendation originally adopted on 1/31/06 with request for additional clarifying language in the report. The report has been revised per the next slide. Panel agreed proposed language addresses concerns raised on 1/31/06.

Dat Recommendation

explaining the important legislative and public policy purposes of the various small business contracting mechanisms and the importance utilizing these mechanisms to ensure smal of granting contracting officials flexibility in Draft Report includes additional language ousiness contracting goal achievements See Draft Report at 34-35

3000

Contracting officers need explicit guidance on how to exercise their discretion in selecting the appropriate small business contracting method for a procurement

Teconorman and the second and the se

Provide guidance clarifying that contracting officer discretion in selecting small business contracting methods should be based on small business goal achievements and market research

Recommendation originally adopted on 1/31/06 but working group agreed to address concern that COs need greater clarification to use the agency goal achievements to guide their discretion. Working group provided this additional revisional to address this concern.

Additional Proposed Amendments Under Recommendation #2

19.201(c) to add the following at the end of paragraph (c): Provide additional guidance in utilizing small business contracting mechanisms, by amending 48 C.F.R. §

agency goals, the contracting officer is provided the discretion in deciding whether to utilize the 8(a) BD, HUBZone or SDVO SBC Programs for a specific procurement. The contracting officer must comply with other statutory and regulatory requirements related to the conduct of market research and the use of the various small business programs. (See Draft Report at the 35.

Additional Proposed Amendments Under Recommendation #2 (Con't)

Redesignate paragraphs (b) through (e) of 13 C.F.R. § 125.2 as paragraphs (c) through (f), and add a new paragraph (b) to read as follows:

goals, the contracting officer is provided the discretior in deciding whether to utilize the 8(a) BD, HUBZone or SDVO SBC Programs for a specific procurement. The In order to achieve the Government-wide and agency

Government's interest business contracting opportunities Cascading procurements fail to with the requirement or the maximum oracticable small balance the

regulations to expressly procurements as an acquisition strategy preclude cascading Amend governing statutes and

Amendment Under Recommendation # 4 Previously Omitted Proposed

Draft Report recommends the repeal of Public Law No. 109-163, which authorizes circumstances (See Draft Report at 37-38 Authorization Act for Fiscal Year 2006, Section 816 of the National Defense cascading procurements in limited the Department of Defense to use

The strategy of reserving prime contract awards for small businesses in full and open multiple award procurements may be effective in providing small business prime contracting opportunities

Provide express statutory authorization for small business reservations of prime contract awards in full and open multiple award procurements that are not suitable for competition exclusively by small businesses

[Recommendation originally adopted on 1/31/06 but implementing language sent back to working group for revisions. The working group revised the language (see next slibe) for 2/23/06 mesting and. Panel adopted revised language and panel adopted revised.

Revised Proposed Amendment Under Recommendation # 8

(C) and (D) with a new proposal to add a revised paragraph (C) to 10 U.S.C. § 2304a(d)(3) and 41 U.S.C. § 253h(d)(3) as follows: The Draft Report replaces the former proposed paragraphs

(3) The regulations implementing this subsection shall -

awards for small business concerns under full and open

Contracting officials need guidance on how to apply the limitations on subcontracting requirements to small business prime contract reservations in full and open multiple award vehicles

Recommendation #9

 Provide an amendment to clarify that the limitations on subcontracting provisions do not apply to contracts that are reserved for small businesses in full and open multiple award procurements and to require that SBA conduct a study on whether the limitations on subcontracting is beneficial in boday's contracting Recommendation tabled pending further discussion!

Proposed Amendments Under Recommendation #9

- Add a new paragraph (4) to 15 U.S.C. § 644(o) to read as
- (4) The limitations on subcontracting do not apply to prime contracts that are reserved for small business concerns under full and open multiple award procurements.

Add a new paragraph (k) to 13 C.F.R. § 125.6 as follows:

(k) The limitations on subcontracting do not apply to prime contracts that are reserved for small business concerns under full and open multiple award procurements.

Cader Recommendation # 9

existing affiliation regulations, including the /ital requirements to large businesses from ostensible subcontractor rule, deter small ousinesses that subcontract primary and ousiness "fronts" because they prevent The Draft Report reiterates that SBA's qualifying as small business concerns (See Draft Report at 51)

Revision to Draft Report Under Recommendation # 9

- Add a new paragraph (4) to 15 U.S.C. § 644(o) to require that SBA's Office of Advocacy conduct a study on the limitations on subcontracting requirements, as follows:
- effectiveness of the contract performance requirements under this section based on conventional industry practices and the Administration shall conduct a study on the benefits and 4) The Office of Advocacy of the Small Business

The contracting community needs explicit guidance on utilizing small business reservations for orders against multiple award IDIQ contracts

Aecomponent and a to the contract of the contr

Provide a statutory and regulatory amendment granting agencies explicit discretion to limit competition for orders to small businesses

[Recommendation originally adopted on 1/31/06 pending technical revision of language. Panel voted to adopt revised language (see next sites) and anguage (see next sites) and anguage (see

Revised Proposed Amendments Under Recommendation #10

The Draft Report revises the proposed amendment to 10 U.S.C. § 2304c and 41 U.S.C. § 253j, governing FAR other provision of law, including but not limited to" in the Part 16 IDIQ contracts, to delete the reference to "any proposed paragraph (c) to read as follows:

(c) Notwithstanding paragraph (b) and Section 803 of Pub. Law No. 107-107, 115 Stat. 1012 (2002), a contracting officer has the discretion to set forth procedures in multiple award contracts that provide that competition for particular orders may be limited to small business concerns, including the subgroups identified in Section 15(g)(2) of the Small Business Act 15 U.S.C. 644(a)(2) 1, Section 15(g)(4) of the Small Business Act 15 U.S.C. 644(a)(2) 1, Section 15 (g) 1, Section 15 (g) 2, Section 15 (g) 3, Section 15 (g) 3, Section 15 (g) 4, Sectio

Next Steps

 Post the working group's draft report, including findings and recommendations, on the Panel's web site for public comment

Acquisition Advisory Panel

REVISED TO SHOW STATUS BASED ON 1/31 DELIBERATIONS

Cross-Cutting Issues: Small Business Working Group

Preliminary Draft Recommendations January 31, 2006

Small Business Working Group Panel Members

- David Javdan, Chair
- General Counsel, U.S. Small Business Administration
- Louis Addeo
- President, AT&T Government Solutions
- Deidre Lee
- Assistant Commissioner for Integrated Technolog
 Somious Redonal Assembition Commission Commission
- * Trought Wallenday
- Acing Senior Proxumenter Executive, Gr

General ssue Areas Analyzed

Adequacy of guidance in structuring
federal services acquisitions to afford
small business participation on the prime
contracting level

 Adequacy of guidance to ensure that small competition for multiple award prime businesses have fair access to

Contracting officers need definitive guidance on the priority for applying the various small business contracting preferences to particular acquisitions

- Amend the Small
 Business Act to provide
 consistent statutory
 language governing the
 applicability of the
 various small business
 preference programs
- Panel Adopted on
 1/31/06 Subject to
 Technical Review o
 Language

Poposed Amendment Clader Clader Amendment Clader Cl

Amend 15 U.S.C. § 657a(b)(2) to resolve any confusion and to ensure that contracting officers have the discretion to award HUBZone set aside and sole source awards:

(2) Authority of contracting officer

Notwithstanding any other provision of law--

(A) a A contracting officer may award sole source contracts under this section to any qualified HUBZone small business concern,

<u>.</u>

A E E L

Contracting officers need explicit guidance on how to exercise their discretion in selecting the appropriate small business contracting method for a

Recommendation #2

- Provide guidance clarifying that contracting officer discretion in selecting small business contracting methods should be based on small business goal achievements and market research
- Panel Adopted on 1/31/06 Subject to Technical Review of Language

Proposed Amendments Under Recommendation #2

Delete 48 C.F.R. § 19.800 (e):

offered to the SBA, SBA regulations (13 C.F.R. § 126.607(b)) SDVO] the contracting officer should review the acquisition with subpart 19.5 [small businesses], 19.13 [HZ], or 19.14 Before deciding to set aside an acquisition in accordance for offering under the 8(a) Program. If the acquisition is give first priority to HUBZone 8(a) concerns

Amend 13 C.F.R. § 124.504(j) as follows:

Amend 13 C.F.R. § 125.19(b) to read as follows:

participation before considering setting aside the requirement If the contracting officer determines that §125.18 does not apply, the contracting officer shall should consider setting aside the requirement for 8(a), HUBZone, or SDVO SBC as a small business set-aside.

Amend 13 C.F.R. § 126,607(b) to read as follows:

Delete 13 C.F.R. §126.609:

precedence. If the criteria are not met for any of these specia contracting authorities, then the contracting officer may solici possibility of making an award to a qualified HUBZone SBC on a sole source basis, and then to a small business under If a contract opportunity for competition among qualified §126.607, the contracting officer must first consider the HUBZone SBCs does not exist under the provisions of small business set aside procedures, in that order of

Agencies need accurate, real-time FPDS-NG data to assess small business goal achievements

Reconstruction of the second of the second

 Direct GAO to conduct a review to determine the accuracy and timeliness of FPDS-NG data

 Tabled for Reconsideration at

-4/3/1/me

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Cascading
procurements fail
to balance the
Government's
interest in quick
contracting with
the requirement
for the maximum
practicable small
business
contracting

Recommendation #4

- Amend governing statutes and regulations to expressly preclude cascading procurements as an acquisition strategy
- Panel Adopted on 1/31/06 Subject to Technical Review of Language

Proposed Amendments Under Recommendation # 4

- Add a new paragraph (I) to 10 U.S.C. § 2304 as follows:
- evaluation of an offer for a contract or for a task or Defense Agencies prohibiting the use of a tiered guidance for the military departments and the (I) The Secretary of Defense shall prescribe delivery order under a contract.
- Add a new paragraph (j) to 41 U.S.C. § 253 as follows:

The contracting community does not properly apply and follow the governing contract bundling definition and requirements in planning acquisitions

Recommendation #5

Provide additional training and create an interagency group to develop best practices and strategies to unbundle contracts and mitigate the effects of contract bundling
 Panel Adopted on

1/31/06 Subject to Technical Review

The Government needs more data on contract bundling to be able to assess and quantify its impact on small businesses

Revise the FPDS-NG data fields to allow for the collection of specified information concerning contract bundling

· Tabled for Reconsideration at

Later Time

Proposed Amendment Under Recommendation # 6

- Require that two data fields be added to FPDS-NG for contracting activities to report:
- The number of small business contracts that were displaced by the bundled action; and
- 2. The projected cost savings of the bundled

Agency officials need targeted training to better acquaint them with the requirements and benefits of contracting with small businesses

Recommendation #7

- Require that OFPP coordinate the development of a government-wide training module on small business contracting and subcontracting with small businesses
 - Panel Adopted on 1/31/06 Subject to Technical Review of Language

The strategy of reserving prime contract awards for small businesses in full and open multiple award procurements may be effective in providing small business prime contracting opportunities

Recommendation #8

- Provide express statutory authorization for small business reservations of prime contract awards in full and open multiple award procurements that are not suitable for competition exclusively by small businesses
- * Panel Adopted on 1/31/06 but implementing language is remarded back to working group for additional work to consider Panel

Poposed Amendment Cloer Recommendation * 8

Amend 10 U.S.C. § 2304a(d)(3) and 41 U.S.C. § 253h(d)(3) to add new paragraphs (C) and (D) to read as follows:

(3) The regulations implementing this subsection shall -

contracts for small business concerns, including the subcategories of small business concerns identified in Section 15(g)(2) of the Small Business Act (15 U.S.C. 644(g)(2)); and (C) establish criteria for setting aside multiple award

Contracting officials need guidance on how to apply the limitations on subcontracting requirements to small business prime contract reservations in full and open rehicles

Recommendation #9

Provide a statutory and regulatory amendment to clarify that the limitations on subcontracting provisions do not apply to contracts that are reserved for small businesses in full and open multiple award procurements

Withdrawn by Morking Group Chair for resubmission with additional language

Proposed Amendments Under Recommendation # 9

Add a new paragraph (4) to 15 U.S.C. § 644(o) to read as

(4) The limitations on subcontracting do not apply to prime contracts that are reserved for small business concerns under full and open multiple award procurements. Add a new paragraph (k) to 13 C.F.R. § 125.6 as follows

(k) The limitations on subcontracting do not apply to prime contracts that are reserved for small business concerns under full and open multiple award procurements.

business reservations explicit guidance on multiple award IDIQ community needs for orders against The contracting

- Provide a statutory and regulatory amendment granting agencies explicit discretion to limit competition for orders to small

Proposed Amendments Under Recommendation #10

paragraphs (c), (d), (e) and (f) as paragraphs (d), (e), (f) and (g) and to include a new paragraph (c) as follows: governing FAR Part 16 IDIQ Contracts, to redesignate Amend 10 U.S.C. § 2304c and 41 U.S.C. § 253j,

Section 803 of Pub. Law No. 107-107, 115 Stat. 101 (c) Notwithstanding any other provision of law, including but not limited to paragraph (b) and 2002), a contracting officer has the discretion I

Amend FAR § 16.504 as follows:

(4) A solicitation and contract for an indefinite quantity must—

issuing orders, including the ordering media, and, if multiple criteria that the Government will use to provide awardees a awards may be made, state the procedures and selection (iv) State the procedures that the Government will use in air opportunity to be considered for each order (see

Amend FAR § 16.505 as follows:

(iii) The contracting officer should consider the following when developing the procedures:

* * * (6) Whether competition for orders will be limited based on socio-economic status.

- Amend DFAR § 216.505-70 as follows:
- (c) An order for services exceeding \$100,000 is placed on a competitive basis only if the contracting officer-
- contractor shall perform and the basis upon which the contracting officer will make the selection, to all small (2) (i) Provides a fair notice of the intent to make the business contractors offering the required services purchase, including a description of the work the

- Amend FAR § 8.405-5, governing the Multiple Award Schedule (MAS) orders as follows:
- (b) Ordering activities may consider socio-economic status when identifying contractor(s) for consideration or competition for award of an order or BPA
- explicitly limit competition for an order to small busi (1) Ordering activities may, in their sole discretion,

Amend FAR § 8.405-2(d), governing the MAS orders as follows:

competition was limited based on socio-economic (d) Evaluation. The ordering activity shall evaluate all responses received using the evaluation criteria provided to the schedule contractors (unless status (see 8.405-5(b)(1)) * ·

- Amend DFAR § 208.404-70, governing the MAS orders as follows:
- notice of the intent to make the purchase, including a description competitive basis only if the contracting officer provides a fair (c) An order for services exceeding \$100,000 is placed on a of the work the contractor shall perform and the basis upor which the contracting officer will make the selection, to-

Statement of Office of Government Contracting and Business Development U.S. Small Business Administration

"Strengthening Participation of Small Businesses in Federal Contracting and Innovation Research Programs"

Wednesday, July 12th, 2006

Thank you for the opportunity for the Small Business Administration (SBA) to present its views regarding strengthening participation of Small Businesses in Federal Contracting and Innovation Research Programs. SBA is focused on creating a better environment for small businesses to thrive and compete through the Agency's government contracting programs. It is well known that when small businesses are thriving, the overall economy is thriving.

Small Business Innovation and Research Program

The Small Business Innovation and Research Program (SBIR) is a set-aside program for small business concerns to engage in Federal Research and Development. Congress created the SBIR Program in 1982 through the Small Business Innovation Development Act. The legislation included four major goals: stimulate technology innovation, use small businesses to meet Federal R&D needs; foster and encourage participation by minorities and disadvantaged persons in technology innovation; and increase private sector commercialization innovations derived from Federal R&D. The Program was reauthorized in 1992 in order to improve and expand the reach of the Program, and again in 2000. The 2000 Reauthorization created requirement for a

searchable public database for the program as well as establishing the Federal and State Partnership Program (FAST).

Businesses eligible for the SBIR program include those that are organized forprofit, small businesses that are at least 51% owned and controlled by one or more individuals who are U.S. citizens, (or permanent resident aliens in the United States) or are at least 51% owned and controlled by another business concern that is itself at least 51% owned and controlled by individuals who are citizens of (or permanent resident aliens in) the United States. An SBIR awardee, together with its affiliates, must have 500 or fewer employees. (CFR SS 121.702)

In keeping with President Bush's policy of promoting innovation, SBA has been reviewing the SBIR program to ensure that it is meeting its goals in today's changing business environment. For example, it appears that some small biotechnology companies may require larger-than-normal influxes of capital to take a product from research to commercialization. Therefore, they have asked SBA to review its policy on venture capital company ownership in their firms as well as others. This process entails researching issues surrounding ownership, control and affiliation rules. There are numerous possibilities and permutations in business structures that can affect whether a company would be considered a small business. SBA is researching this situation carefully to ascertain the needs of today's business environment.

SBA appreciates the information and comments provided by the Government Accountability Office and industry groups, including venture capital and biotechnology groups involved in SBIR awards. Input from Federal agencies as well as state and local governments involved in promoting innovation and research have also been helpful in looking at this complex issue.

Federal Contracting

In the past few months the media has been discussing the SBA's methodology for the Goaling Report and what is included in the report. Here are the facts. Contracts not subject to the Federal Acquisition Regulations (FAR) are exempt from Small Business goaling. Examples include use of non-appropriated funds, certain agencies (Transportation Security Agency, Federal Aviation Administration, etc). A full explanation and list of what is exempt can be found in SBA's Goaling Guidelines document on www.sba.gov. These guidelines are published in the Federal Register.

The Federal Procurement Data System-Next Generation (FPDS-NG) is the official source of Federal Government contracting data. The General Services Administration (GSA) is responsible for maintaining the database, but each Agency is responsible for the information submitted into the database, including socio-economic information. Each Agency's Senior Procurement Executive certifies that its procurement data for the fiscal year has been entered into FPDS-NG, and is as accurate as possible.

Studies by the Office of Advocacy and the Center for Public Integrity show that Agencies are taking credit towards their small business goals for contracts held by large businesses. However, SBA's ongoing review of the underlying data shows that the firms receiving those contracts were legitimate small businesses at the time of award but grew to be large or were acquired by large businesses over the life of the contract. Until this past year, our size rules provided that the size of a business was determined at time of

award. This approach was designed to increase the number of government contracts awarded to small businesses to help them grow, recognizing that Agencies award contracts to small businesses without knowledge of what mergers or acquisitions might take place in the future.

While SBA appreciates the efforts of the Inspector General (IG), we must also point out that the report itself admits to flaws in the source data and can only, at best, refer to the contracts in question as "possible bundlings." SBA made a significant effort to remind the IG that the use of definitions and the reporting requirements are being improved and that the data in question may contain errors. SBA's 2003 Report to Congress on Contract Bundling illuminates this problem. While 2,307 contracts were reported as "bundled contracts," only 94 were "new definitive contracts" that conform to the reporting requirement. The remaining actions are modifications to existing contracts or orders under indefinite delivery contracts, items that should not be classified as "bundled contracts." Consequently, SBA believes that the number of unreviewed bundled contracts was overstated by the IG and we again emphasize that we are making significant progress in identifying and remedying all instances of bundling.

It is difficult for the Agency to respond given that the IG has stated that "many of the reported bundled contracts may not actually have been bundled" and that the IG has misgivings about the integrity of the source data. In fact, in a separate review of SBA effectiveness, the IG noted that SBA consistently appraised all six parts of the bundling analysis and appropriately challenged unsupported bundled contracts 100% of the time.

SBA is Implementing Stronger Guidlines

Well before either of these studies was published, SBA and the Federal government took many steps to address the problem of large businesses competing for small business contracts.

In May 2004, SBA published a final rule that requires businesses that received contracts as small businesses and then need to novate their contracts, usually due to being purchased by another firm, to recertify their size. This rule became effective on December 21, 2004. This would address many of the concerns.

SBA also works with the Office of Management and Budget, GSA and the Department of Defense to continually improve the accuracy of the Central Contractor Registration (CCR) database. All firms are required, among other things, to certify annually that the information provided and representations made (including with respect to size) are accurate. In addition, SBA is preparing a final rule that addresses small business size status recertification for long-term contracts.

Additionally, stronger penalties for businesses who intentionally misrepresent themselves were requested in the Agency's FY 2007 legislative package.

What Small Businesses Should Know

We appreciate this opportunity to educate small businesses on what they can do.

When a small business believes a large business is getting a contract intended for small business, it should file a protest with the contracting officer. This will initiate a review by SBA. This is not a complex process, and there are minimal costs. When a business is found to be other than small, it may not be awarded the contract.

The amount of Federal prime contract dollars going to small business has increased from \$43 billion in FY 2000 to \$80 billion in FY 2005. In FY 2005 the Administration has again surpassed the statutory goal with 25.4% of prime contracting dollars going to small businesses. The Department of Defense, the leading purchaser of goods and services, awarded \$53.8 billion of its contracts, or about 24.6 percent, to small businesses. The FPDS-NG report showed that the government surpassed the 5 percent goal of contracts going to small disadvantaged businesses. Participants in SBA's 8(a) Business Development Program received \$10.5 billion in contracts, a 25 percent increase over the previous year. Firms in the Historically Underutilized Business Zone (HUBZone) program received \$6.1 billion in contracts, a 27 percent increase over the previous year. Contracting dollars awarded to women-owned small businesses increased by \$1.4 billion to a record \$10.5 billion, a 15 percent increase over the previous year. Contracts to service-disabled veteran-owned small businesses increased significantly, reaching \$1.9 billion, up from \$1.2 billion in FY 2004 and a 58 percent increase over FY 2004.

SBA will strive to ensure that small businesses continue to have the opportunity to compete and thrive in the marketplace. SBA appreciates the opportunity to learn from small businesses, industry and entrepreneurs though discussions like this. We look forward to working with this Committee to reauthorize SBA's programs that are important to small businesses.



Before the Committee on Small Business and Entrepreneurship United States Senate
July 12, 2006

Statement of Patricia Rice Director Maine Procurement Technical Assistance Center

RE: DOD Commercialization of SBIR/STTR and the link to acquisition programs

Madame Chair, Senator Kerry, thank you for the opportunity to provide testimony on Section 252 of the National Defense Authorization Act regarding a Commercialization Pilot Program to accelerate the transition of technologies, products, and services developed under the Small Business Innovation Research Program (SBIR) to Phase III, including the acquisition process.

My name is Patricia Rice, Director of the Maine Procurement Technical Assistance Center. The Maine Procurement Technical Assistance Center helps Maine small businesses obtain government contracts with the Department of Defense, other federal agencies, state and local governments, and prime contractors. Last year, Maine small businesses sold over \$129 million in goods and services to the government market. The SBIR/STTR program has significantly benefited small businesses in Maine. Maine small businesses have received over \$25 million in R&D funding since 1999. Small businesses in 13 of Maine's 16 counties have received SBIR/STTI funding.

The Procurement Technical Assistance Centers (PTACs) and the Maine PTAC support the objectives of Section 252 of the NDAA. PTACs can play a critical role in assisting the Department of Defense to implement this new directive. The Procurement Technical Assistance Program is administered by the Defense Logistics Agency, on behalf of the Secretary of Defense. PTACs are a local resource available that can provide assistance to business firms in marketing products and services to the Federal, state and local governments. The PTAP, is the one federal program that directly and effectively offers a

concrete bridge between small businesses throughout the United States and Department of Defense and other federal acquisition offices.

PTACs are uniquely positioned to harvest the technologies supported through DOD SBIR awards to small business and to link them to on-going DOD acquisition programs. For example:

- PTACs are already a DOD small business program
- PTACs have strong ties and relationships built with DOD Prime Contractors that will be needed to get the SBIR/STTR technologies inserted into on-going contracts.
- PTACs are a nationwide organization that can reach even the smallest and newest technologies being developed by small business. In addition, the PTACs present a unified approach unlike the current patchwork of outreach.
- PTACs are capable of making the connections that small businesses may need in
 order for them to begin talking with DOD Prime Contractors—concerns about
 intellectual property and licensing are paramount but we could also connect small
 businesses with DOD testing facilities and programs. Both IT protection and
 additional testing would have to be part of the issues that would need to be
 addressed—beyond Phase II.
- PTACs do believe that a comprehensive program is needed as well and could
 work with program managers, DOD research facilities and others to bring about
 the commercialization with the end result being inserting of DOD supported SBIR
 technologies into DOD programs and for the small business an acquisition prime
 contract with DOD or a subcontract with a DOD Prime
- The Region 1 PTAC which includes CT, MA,ME, RI, NH, and VT have had numerous Matchmaker Events, we have cooperated with Raytheon in some of their outreach events, we have patent programs at Brown University, University of Massachusetts, University of New Hampshire and University of Maine that in the past have assisted small businesses connected with the SBIR program. Massachusetts in particular has a large number of DOD SBIR awardees as well as many DOD Prime Contractors.
- PTACs have a well documented history of success in providing procurement technical assistance to small businesses nationwide. This includes a track record of successful assistance in commercializing technology to the Dept. of Defense.
- PTACs core competency is in the commercialization of technologies.

We believe that given some additional resources from DOD that are called out in the new directive of 1% for outreach, that PTACs could work even more effectively with DOD program managers, DOD acquisition process, small business DOD SBIR awardees and the other elements that would include IP protection and a testing program.

Thank you for the opportunity to provide a statement on this important issue.

SBIR, RENEWAL AND U.S. ECONOMIC SECURITY

Roland Tibbetts

Congress will shortly consider some changes in the federal SBIR and STTR programs including venture capital participation and renewal of the legislation. These are important to consider. More important is the need to increase the participation of innovative small high tech firms in government R&D. In contrast to other government R&D, they focus on technological innovation and technology breakthroughs that the nation needs for economic growth and security. Consider our continuing loss of manufacturing, millions of related jobs, and a trade deficit at record levels with no apparent solution in sight. Many economists and industrial leaders have spoken out on the importance of technology-based innovation.

The Small Business Innovation Research program was designed specifically to increase technology-based innovation in 1977 at NSF. It was extended government-wide by Congress and signed by President Reagan to the 11 largest R&D agencies in 1982. SBIR has grown steadily and received favorable performance reviews by GAO, Dr. Josh Lerner of Harvard Business School, and the National Research Council of the National Academy of Sciences.

Total scientists and engineers employed in R&D in industry	10,920,523	100%
Employed by firms with 500 or less employees	5,986,524	54.8
Employed by firms with more than 500 employees	4,933,999	45.2
	(000)	%
Total Extramural Federal R&D Expenditures (net of R&D Plant \$)	\$ 81,675,000	100.0
Industry expenditures of federal R&D dollars total	44,577,000	54.6
By firms with 500 or less employees	3,527,000	4.3
By firms with more than 500 employees	41,050,000	50.3
By firms with more than 500 employees directly	39,411,000	48.3
Plus FFRDC R&D by firms with more than 500 employees	1,639,000	2.0
Total federal R&D performed by large firms	41,050,000	50.3
By universities	23,900,000	29.2
Plus FFRDC's R&D administered by universities	4,955,000	6.1
Total university R&D	28,855,000	35.3
By non-profits	5,972,000	8.1
Plus FFRDC R&D administered by non-profits	1,464,000	1.9
Total non-profit R&D	7,436,000	10.0
States and Foreign	\$807,000	1.0
Source: "Science and Engineering Indicators 2006" figures for 2005		

Small technology firms with 500 or less employees now employ 54.8 percent of all scientists and engineers in US industrial R&D. However, these nearly 6 million scientists and engineers are able to obtain only 4.3 percent of extramural government R&D dollars. In contrast, large and medium firms with more than 500 employees combined employ only 45.2 percent but receive 50.3 percent of government R&D funds. Universities receive 35.3 percent, non-profit research institutions 10.0 percent, and states and foreign countries 1.0 percent. Of the 4.3

percent that goes to small firms 2.5 percent is from SBIR and the related Small Business Technology Transfer (STTR) program. Together they receive less than 10 percent of the funding that large firms receive.

Paul Romer, Stanford University economist, has said that his research shows that the key determinant of economic growth is not tax rates or monetary policy, but the pace of technological innovation. Small firms have clearly been a significant factor in US technological innovation.

A major question is -- Why do Federal agencies continue to severely limit their funding to small firms? It is the small firm that moves quickly into new and emerging areas, that can raise tens of millions of venture capital, are more innovative, efficient and lower cost. We need to think about what firms founded since 1960 have done -- in Silicon Valley, around Route 128 near Boston, in San Diego, Austin, Atlanta, Minneapolis, Seattle and in most major cities and research university locations. Many of these startups have become world leaders in their field. Their technology and products have made an enormous impact on our quality of life, and the world's. They are also responsible for many billions of dollars of investment and sales, and millions of quality jobs directly and much more indirectly. In contrast, our large industrials are moving their manufacturing jobs rapidly to China and other low wage countries.

Why is it that with this track record in innovation, our technological competitiveness in new areas and related economic growth that federal funding to small tech firms is so limited? After 24 years at NSF working with most federal R&D agencies, I believe it is the direct result of continuous opposition from the traditional recipients of government R&D, their associations and lobbies, to get more and retain or increase their percentage of federal R&D dollars. It is not all technical merit or the importance of their research to the country. New economy-related technology breakthroughs are at least as important in our current environment. It is political power that wins. Many federal agencies seem to be wedded to this same tradition and also oppose increasing the proportion going to thousands of small high tech firms that have little political power to improve their situation. Some of this difference is understandable, but the enormous degree of difference is not.

Thousands of small firms and their research scientists and engineers are brilliant, extremely innovative, competent and motivated. They and the firm must be innovative to succeed and survive. They want to pursue technological innovations and breakthrough ideas, particularly in emerging areas. Seeking innovation and technology breakthroughs is high risk, probably equal to that in basic research and much other government R&D, too high for most private investors, large firms and venture capitalists.

I believe there is a national need for our economic security to seek technology breakthroughs. I also believe that small high tech firms are the most effective and efficient strategy to do this. The very high risk requires a source for funding cutting-edge research for new breakthrough ideas at the idea stage where there is financial market failure. The risk is simply too high, as it is for basic research, for private sources.

This is what SBIR and STTR were designed to do. The goal is to find promising new ideas, select the most promising, fund early research to explore technical feasibility and lower the risk to levels more acceptable to private investors. It is extremely difficult for small high tech companies to find initial funding for innovative ideas, particularly in new and emerging fields, in areas extremely important to the nation's future. The computer, software and biotech revolutions are good examples.

As problems have become more challenging, initial funding at the idea level has become steadily more difficult to obtain from venture capital firms and others. The stock market crash of 2000 increased the resistance of potential investors to this type of funding. VC's generally want to see that the idea is technically feasible before investing and better yet, that is on the market and looks promising.

The SBIR approach may be the most effective and efficient way to fund small high tech firms to meet this need. It is a legislated program now embedded in 11 agencies, with significant collaboration with research universities and the venture capital industry. It is known and understood by tens of thousands of scientists and engineers in small firms, government and universities, and by others in venture capital, large firms, Congress, and all 50 states. The 3-phase program is extremely competitive with only about one of 16-20 original proposals submitted in Phase I receiving the larger funding in Phase II. Phase III support must come from private investors or from non-SBIR/STTR funds from such agencies as Defense and NASA.

Most breakthroughs in emerging fields do not come from large firms. This was the case with smaller computers, software, Internet applications, and biotech. Individuals and small high tech firms contribute disproportionately to innovation and technology breakthroughs. Large firms focus more on improving their competitiveness, sales and profit margin of existing products or services and adding related new items. Most small high tech firms were founded to chase a new idea or need. They seldom can compete with large firms in their product areas. However, breakthrough ideas from startups in emerging fields created most of the industry leaders such as Intel, Microsoft, Apple, Dell, Cisco Systems, FedEx, Amgen, Medtronic, Genentech, Ebay, Amazon and thousands of others of all sizes. Symantec started with an SBIR award. Qualcomm received 12 SBIR awards totaling \$1.6 million when it had about 35 employees. SBIR also creates acquisitions such as Orincon, now Lockheed Martin Orincon. It received 130 SBIR awards over 16 years totaling \$35 million. By 2003 sales had increased to \$60 million, it had four suitors. Some 800 firms with SBIR awards have been acquired by other companies.

Small technology firms are often more creative and faster at converting innovative ideas into new products. More importantly, they stimulate billions of private investment, millions of quality jobs (6 million scientists and engineers alone as stated earlier) and enormous economic impact. They also become a valuable national farm-system for acquisitions by other firms and for the venture capital industry investment. Many large companies, such as DuPont, for example, have acquired more than 100 companies, most of them small.

Response time is increasingly important. We are living in a faster changing and far more competitive economic world that favors the innovativeness, speed and lower costs, all features of the small company, particularly in emerging fields. The most critical problem they face is the unwillingness of investors to fund cutting-edge research at the idea level as mentioned before. Our small high tech firms are still a unique national asset but not if they cannot find investors at the idea stage. Government investment in stimulating high risk innovative and breakthrough ideas would appear to be appropriate to strengthen our economic security — and a useful strategy. SBIR does this by funding the gap between promising ideas and private investment. It focuses directly on the key problem — the shortage of initial funding needed to explore thousands of promising new ideas and lower the risk to levels acceptable to follow-on private investors, often VC firms. Further success can lead to Initial Public Offerings (IPO), secondary offerings or even acquisition by another firm as frequently happens.

I have been asked - Why can't large firms or universities solve our innovation problem just as well? The answer is the eventual need for large amounts of high-risk investment to move an

idea all the way to the marketplace. Large firms usually will not take this risk in new or emerging areas because the risk is too high. Only small firms with low stock values and capitalization can attract the needed investment. With success a small company's stock can multiply in value and time by 10-50 or more times. The investor in high-risk projects needs the potential for the stock to multiply many times, sufficient to offset the risk. A major success can result in enormous increases in stock value and personal wealth for many that are involved. Most large firms cannot take such risks. Their appreciated stock cannot multiply in value enough even if the idea is successful. They also cannot afford failure and what it would do to their profit projections. Seldom do they invest large amounts in ideas outside their existing product lines or in new fields. Instead, they may wait and buy or merge with a firm that has made a breakthrough in a field of interest, after it has proven successful.

Interestingly, many of our most creative scientists and engineers prefer to work in small high tech firms. They want to work on "their" ideas without being controlled by layers of superiors, team effort compromises, or other corporate priorities. Bill Gates is an excellent example some of the best and the brightest prefer to work in or start their own small company. He knew what was necessary and IBM did not, in his opinion. He also intended to do what he felt needed and do it faster, more effectively, and at far lower cost. It is an example of why many small firms have been the best vehicle for converting breakthrough ideas into successful new products and services. That is the opportunity that SBIR and STTR funding provide to thousands of scientists and engineers.

There are good reasons for increasing the funding of SBIR increasing with the renewal of legislation. We face an enormous loss of manufacturing jobs and significantly increased competition in technology and innovation. We must consider our problems with our trade deficit and increase our interest in our economic security and competitiveness. There is a need to accelerate our research seeking technology breakthroughs, particularly in new fields. Raising large amounts of high risk capital to finance cutting-edge research is critical to this process. Universities or large firms are not ideal because they cannot raise the required follow-on capital.

The three key players are small high tech companies, venture capital firms, and research universities. The SBIR and STTR design involves all three. Currently we have an advantage as the US now leads the world in each category. SBIR/STTR funding of the initial cutting-edge research to explore the technical feasibility of the idea, often in collaboration with university scientists, is the key factor to start the process. VC firms are interested in the results and often will invest in the firm if results are promising. STTR requires joint-university collaborative projects to increase needed university/small tech firm collaboration. The approach also is aimed at increasing the economic return on our investment in basic research. However, the problem is that - If there is no initial investment at the idea stage, there is no economic result.

The SBIR design is a result of my reading about 50 articles and papers on innovation, technology breakthroughs, and best R&D practices. I also had discussions with many economists including some specializing in innovation, many VC people, some in large firms, universities, federal government specialists, and others. There were a number of visits to Silicon Valley and Route 128 firms, to VC people and to 12 or so major technical universities both before and after I joined NSF. I talked at length with people from MIT, Harvard Business School and Stanford and have had many discussions with many specialists in NSF, SBA, Defense, NASA and NIH. In the federal program there was careful coordination with SBA and later the Small Business Committee staff in the House and Senate, in GAO, and with intellectual property experts. Prior to joining NSF I had been VP of two small to medium-sized

technology companies for 13 years and a founder and director of Allied Capital. I was well aware of the problems of small tech firms in obtaining financing for new ideas.

SBIR was carefully designed to increase the opportunity for small firms to participate in federal R&D. It has but 2.5 percent spread over 11 agencies when there are more scientists and engineers in R&D in small firms than large is probably not what is best for the country. It was also to increase the economic return from government research and R&D. Another objective is from the beginning was to prevent the funding of marginal research. It is a three-phase program that stops continued spending on less promising ideas. First, It is very competitive with only one out of 8-10 Phase I proposals funded. This provides an initial investment limited to \$100,000 for six months of research to determine as quickly as possible if an idea appears to be technically feasible -- and the quality of the research. It requires a new more comprehensive proposal for Phase II based on Phase I results. The objective is still technical feasibility I but also its commercial potential. About 40-50 percent are funded for research or R&D up to \$750,000 and two years. No further SBIR funds are spent. Phase III must be privately funded unless Defense or NASA, for example, is the customer, and they fund Phase III with non-SBIR funds. SBIR money only funds advanced high-risk research of interest to the agency. Private investment then funds the product development and commercialization. The quality of research has been high.

While the goal was to focus directly on the critical problem in obtaining initial funding at the idea stage, there were other important objectives, too. These included opening up almost all federal R&D to small high tech firms. This was not possible prior to SBIR. It provided quality small companies with a potential source of cutting-edge research funding that is critical for high tech firms. It was often impossible for a small firm to obtain prior to SBIR. Other goals included focusing more government R&D on innovation and emerging areas, particularly those that have economic and commercial potential. There is a continuing need to encourage university/small tech firm collaboration that needs to be expanded. It was also critical to insure a first-rate and efficient review process in order to select the best proposals and to provide the company with intellectual property rights. SBIR gave small firms (and universities) that right and was the basis for the Bayh-Dole Bill in 1980, three years after SBIR began at NSF in 1977.

A major objective of the program as stated earlier was to provide the initial funding for ideas prior to venture capital to reduce the severe financing gap that faced almost all small high tech firms. It has done so for those that received awards and significantly increased the interest of VC's, large firms and other potential Phase III investors. A technology breakthrough in a promising area can result in significant growth and profit wealth for the company, and wealth for key employees and investors and the related taxes from this government investment. SBIR/STTR not only help companies interested in breakthroughs find capital, but also it helps attract creative and brilliant scientists and entrepreneurs to start or join small high tech firms.

When the technical risk is too high to attract private investment, as it is for most breakthrough ideas, government funding should be appropriate, as it is for basic research, defense, space, health, and home security. Why not for economic security as well?

SBIR is a valuable lever to stimulate technological innovation and technology breakthroughs, faster, more effectively and at lower cost than possibly any other approach.

I suggest the following changes be considered on renewal:

- There is a need to increase the size limit of awards to \$150,000 in Phase I and \$1 million in Phase II with no exceptions for agencies. To allow higher limits for some will be exploited by some companies and unfair to others. If a small firm cannot attract follow-on private or non-SBIR funding after spending \$1,150,000 of government funds on a project, it should fund other promising projects. If an agency feels that a project's merit justifies more investment, then it can do so in Phase III with non-SBIR funds. Larger awards significantly reduce the number of awards and therefore the number of ideas and companies that can be funded, such as \$2 million Phase II's would reduce the number of awards by one-half. If higher limits are allowed for one agency the same limits will soon be requested and often approved by others. Innovation and breakthrough R&D is increasingly expensive and salaries have increased since 1996. SBIR is not intended to cover all costs but rather fund early research on technical feasibility to reduce the risk and increase the interest of follow-on investors. The limit is also necessary to prevent exploitation by some companies and VC firms. Larger award limits will encourage many firms to seek the maximum simply to obtain as much funding as possible from government, rather investing private funding. If started, this practice would be difficult to stop by SBA or other agencies. I suggest that NIH, and maybe only NIH, should be able to use additional SBIR funding for project-related efficacy, toxicology and other studies required by law.
- 2. A successful small firm should not be denied eligibility to propose ideas to SBIR as long as the total number of employees in all affiliated firms, including all companies controlled by the VC firm, is 500 or less employees. SBIR is designed to attract venture capital. VC firms at times acquire more than 50 percent ownership in an SBIR firm particularly with follow-on investments and this should not deny participation. However, SBIR awards must be made to legitimate small companies to be fair to all competitors and SBIR firms must not be directly or indirectly controlled by large venture capital firms or by any large companies.
- 3. <u>I suggest that SBIR be increased by 0.5 percent annually until it reaches at least 5.0 percent over the next five years and STTR by 1.0 percent annually until it reaches 5.0 percent also over same five years. We need to significantly increase university/small tech firm collaboration to achieve technology breakthroughs. STTR must be significantly larger to attract research universities' collaboration. This would mean that about 40 percent of STTR funding would be going to universities or 2 percent of the 5 percent of STTR. STTR firms would receive 60 percent of STTR awards funding equal to 3 percent of extramural federal R&D. Therefore total federal R&D going to SBIR and STTR would gradually increase to 8.0 percent by 2012. Our 6 million small technology firm scientists and engineers in small technology firms are an important US asset and we need to increase their participation in federal R&D.</u>
- 4. There is great need to increase the number of SBIR/STTR_staff in SBA. No program of this size can be administered with 5-6 employees. The criticism of SBIR performance when grossly understaffed is unfair. It has been steadily reduced to 5-6 people, about half of what it was when the program was half its current size. SBA must have more resources to conduct the program properly as Congress intended. This should be reviewed and evaluated by an independent specialist in this field.

Roland Tibbetts was SBIR Program Manager at the National Science Foundation from 1976 to 1996 and retired that year.

June 28, 2006



Statement of Women Impacting Public Policy

Submitted to Senate Small Business and Entrepreneurship Committee

"Strengthening Participation of Small Businesses in Federal Contracting and Innovation Research Programs"

July 12, 2006

Madam Chair and Members of the Committee, Women Impacting Public Policy is pleased to submit its views concerning federal contracting and procurement assistance programs for small businesses. Women Impacting Public Policy (WIPP), a bipartisan nonprofit organization, represents 550,000 women in business nationwide and 42 small business associations.

Thank you for holding this hearing today on a very important issue for small businesses across the country- federal contracting. Although recent statistics released by the SBA show that the federal contracting goal for small businesses of 23% was exceeded in FY05, the goal for women-owned businesses continues to be lower than the goal of five percent—in FY05 only 3.3 percent of federal contracts were awarded to women-owned businesses. We believe, however, that the federal government could meet its goals if resources were increased and changes to acquisition policy were enacted.

As Congress moves to reauthorize the Small Business Administration's (SBA) programs this year, there is one glaring problem—adequate funding for SBA staff that can provide procurement assistance. The number one issue for small businesses who want to enter the federal market is an understanding of how the federal buying system works and the ability to respond to a federal sales opportunity. Not only is marketing expertise required, but also an array of other complex issues. It is essential that small businesses understand teaming agreements, mentor protégé programs, the correct way to respond to Requests for Proposals, the complex acquisition rules, and the different kinds of contract vehicles. The amount of expertise required to be a successful contractor to the government can be overwhelming.

The SBA regional offices should be prepared to provide this assistance but the reality is that there is inadequate staff to provide procurement expertise to small businesses. In addition, WIPP members report to us that while some SBA offices are able to introduce them to federal installations in their region and are knowledgeable about upcoming procurements, many are unable to do so. We believe this to be largely due to whether or not Procurement Center Representatives (PCRs) are located at that facility and whether or not an SBA staffer is properly trained to understand government procurement. PCRs are charged with reviewing agency contracts and have the ability to review subcontracting plans and compliance with those plans. With a bare bones staff, this requirement is neigh to impossible. There is a financial incentive to the government to increase the PCR program. In the "FY2004 SBA Breakout Procurement Center Representatives Report to Congress," it showed that a team of eight employees in the Breakout PCR program saved the federal government \$2.52 billion from FY85 through FY04 in lower costs and prices.

According to WIPP's 2006 Annual Member Survey, 68% of respondents believe that the number of PCRs should be increased. WIPP applauds the efforts of the Senate Small Business Committee to ensure adequate funding for additional PCRs beyond the six requested in the FY07 President's budget.

Putting aside any philosophical discussion on whether competition should be restricted to minority, women, HUBZone-certified or veterans, the practical reality is that unless federal agencies are required to do so, it will not happen. For example, the Congress has given the federal agencies a goal to meet of awarding five percent of all federal contracts to women-owned businesses. The most recent number shows that only

three percent of all federal business is awarded to women-owned businesses. That represents billions of dollars, according to an annual report prepared by the House Small Business Committee Minority Staff. So, if the goal is not a mandate, it simply will not happen. It is in the category of "nice to have" but there is no penalty to the agencies or the federal employees if the agency fails to meet the woman-owned goal.

The SBA on June 15, 2006 published a proposed rule to implement the Women-Owned Small Business Federal Contract Assistance Program as outlined in Public Law 106-554. The program, as stated in the proposed rule, would allow contracting officers to restrict competition for women-owned businesses. The proposed rule establishes a framework for implementation of the program. However, this rule will not be implemented until the study identifying industries in which small business concerns owned and controlled by women are underrepresented with respect to federal procurement contracting is completed. We would note that the women's business community has been waiting for six years for completion of this study. WIPP will be submitting comments on the proposed rule by the July 17th deadline.

We have said for as long as WIPP has been in existence that P.L. 106-554, the law authorizing the Women-Owned Small Business Federal Contract Assistance Program, must be implemented in order to meet the five percent target for women-owned businesses identified by Congress. This is a critical tool to helping women-owned businesses grow and diversify into the federal marketplace. Furthermore, WIPP members believe that the contracting goal of five percent should be increased. According to WIPP's 2006 Annual Member Survey, 66% believe that the five percent goal for women-owned business contracting should be increased.

In the absence of restricted competition for women-owned businesses, the tool most often cited by the federal agencies is to "go get your 8(a) certification." And yet, it is abundantly clear to WIPP that the SBA presumes that women business owners are not really socially and economically disadvantaged. One only needs to go through the tedious process of assembling reams of financial documents, personal stories dating back decades to be awarded an 8(a) status. In effect, while the SBA touts the electronic application as an improvement, the accompanying paper documentation for womenowned businesses requires a staggering number of binders to support the evidence.

In the past, "clear and convincing evidence" was the standard which made it almost impossible for women-owned businesses to get into the 8(a) program. In the late 1990's, that standard changed to "preponderance of evidence" in order to facilitate the entrance of women-owned businesses into the program. It seems to our members that SBA has reverted back to the old standard. If the SBA believes that women who are not minorities should not qualify, they should just say so. It would save our members hundreds of hours of paperwork and valuable dollars.

While we are on the subject of the 8(a) certification, we note that the income thresholds have not been updated since 1989. That presents a real problem for the program—the thresholds are so low in 2006 dollars that the program is really set up to fail. If a business owner does not have assets on which to draw, the business is less likely to succeed.

We look to Congress to reverse the trend toward contract bundling that still occurs despite the President's initiative in 2002 which clearly stated that unbundling of contracts was a priority of this Administration. When the President launched the

initiative in 2002, the Office of Management and Budget (OMB) reported that for every \$100 awarded on a bundled contract, there is a \$33 decrease to small businesses. They went on to say, that because these types of contracts "run longer and encompass a greater scope, competition is reduced in terms of frequency and the number of opportunities" for small business. Despite strong evidence that bundling is not good for small business or the government, a 2004 Government Accountability Office (GAO) Report No. 04-454 "Impact of Strategy to Mitigate Effect of Contract Bundling on Small Business Is Uncertain", shows that federal agencies are confused over what constitutes "contract bundling" which results in poor accountability and disparity in reporting. While 928 bundled contracts were captured in the Federal Procurement Data System (FPDS), only 24 of those contracts were reported by agencies to the GAO. We urge the Committee to clear up the confusion for the agencies and continue its efforts to unbundle contracts.

One of the most troublesome trends is "strategic sourcing" which in most cases ends up meaning "bundling." Strategic sourcing basically means that a very large contract will have only one source or company which can sell to the government as opposed to an award to multiple vendors. Small businesses can be harmed in two ways. One, by structuring a procurement to be so large that even a team of small businesses could not win the contract, small businesses lose out on the contracting opportunities. This is especially true in the area of office products where small businesses are licensed resellers and provide the support required through maintenance of the equipment.

Second, selection of a single vendor cuts out many small businesses that would be eligible for subcontracting opportunities if multiple vendors were awarded the contract. Basically, if the small business does not align itself with the winner, they are out of luck.

Another issue which is tremendously confusing to small businesses is the "non-manufacturer" rule and the waivers required by SBA. SBA's website on the non-manufacturer rule states "Section 303 (h) of Public Law 100-656 and Section 210 of Public Law 101-574 incorporated into the Small Business Act requires that agency contracts be directed solely to small business manufacturers under set-aside provisions. This requirement is commonly referred to as the Nonmanufacturer Rule. The Small Business Act also contains provisions that allow the Administrator of the SBA to waive this requirement when there are no small business manufacturers or processors available to supply the product to the Federal Government. The Administrator has delegated the authority to make decisions on waivers of the Nonmanufacturer Rule to the Associate Administrator for Government Contracting in the following cases:

- after reviewing a determination by a contracting officer that no small business manufacturer or processor can reasonably be expected to offer a product meeting the specifications (including period of performance)
 required of an offeror or by the solicitation; or
- for a product or class of products after determining that no small business
 is available to participate in the Federal procurement market.

These two types of waivers of the Nonmanufacturer Rule are regularly referred to as "individual waivers" or "solicitation-specific" and "class waivers."

The nonmanufacturer rule, which is designed to help small businesses is hurting small businesses particularly in the area of technology products. The waivers are granted by the regional SBA offices. But there is much confusion on how the waivers are administered and when the law applies. For example, if a small business assembles

technology components but is not the Original Equipment Manufacturer (OEM), does the small business need a waiver? If that is the case, and waivers are not granted, small business resellers have just been cut out of a large segment of the federal market. We urge the Committee to review this rule and clarify how it should be administered.

With respect to the small business offices, known as the Office of Small and Disadvantaged Business Utilization (OSDBUs), we urge the Committee to empower these small business advocates within federal agencies whose work is invaluable to small business contracting. The law which established these offices, P.L.95-507, clearly states that the Director of the OSDBU office should "be responsible only to, and report directly to, the head of such agency or the deputy of such head, except that the director for the Office of the Secretary of Defense shall be responsible only to, and report to, such Secretary or the Secretary's designee." The OSDBUs are required to identify proposed solicitations that involve bundling and with the agency to revise those contracts to increase small business participation.

In reality, many OSDBUs do not report to the Secretary/Director of the agency and do not have the authority to influence agency procurements to any real extent. In many cases, they are relegated to a lowly position with inadequate budget and no meaningful oversight of procurements. And, yet the OSDBUs are the voice of small business within the agencies. We believe that only Congressional insistence and oversight will turn these critical offices into the defenders of small business that Congress envisioned.

Thank you for this opportunity to submit WIPP's comments on federal procurement programs affecting small businesses. We look forward to working with the Committee on the SBA Reauthorization bill.



STATE OF MAINE DEPARTMENT OF ECONOMIC AND COMMUNITY DEVELOPMENT



JOHN ELIAS BALDACCI

Jack Cashman

July 12, 2006

U.S. Senate Committee on Small Business and Entrepreneurship Senator Olympia J. Snowe (R-ME), Chair c/o Max V. Kidalov, Counsel 428A Russell Senate Building Washington, DC 20510

To Senate Chair Snowe and Distinguished Members of the Senate Committee on Small Business and Entrepreneurship:

Unfortunately, I cannot be there to testify before your committee. Therefore, I am writing to strongly endorse the Small Business Innovative Research (SBIR) Award program, and respectively request that you consider its expansion. SBIR awards provide critical capital for early stage, industry-driven research at a stage when other sources of capital are unavailable to small businesses, especially as traditional forms of debt and equity financing become more risk averse. SBIR is the single best program for stimulating research and development (R&D) activity in U.S.-based small companies. In addition to stimulating the development of new products and services needed by federal agencies, SBIR awards fuel innovation nationwide by supporting R&D leading to commercialization at a time when continuous innovation is becoming increasingly important for U.S. competitiveness. It is through innovation that standards of living will continue to rise, that new industries will emerge and our traditional industries will regain or maintain their competitive position.

SBIR awards have been very important to Maine's developing Innovation-based economy. Prior to 2000, Maine averaged approximately 12 SBIR awards totaling \$1.2 million annually. Since that time, Maine has increased its receipt of SBIR awards to more than 20 per year, averaging over \$5 million. This increase corresponds to an increase of \$100 million annually in Maine's industry-led R&D activity. SBIR awards have leveraged state and private resources to significantly increase Maine's overall R&D activity to \$430 million annually, or just over 1% of Maine's gross state product (GSP). Continual support for small companies' early-stage R&D activity, such as that provided by the SBIR award program, is needed if Maine is going to continue this trend and reach our goal of R&D activity equivalent to 3% of GSP.

59 State House Station • Augusta • Maine • 04333-0059 Phone: (207) 624-9800 • Facsimile: (207) 287-2681 • TTY (207) 287-2656 www.econdevmaine.com Factors that contribute to the success of the SBIR program include:

- Rigorous, competitive process based on technical merit, fit to national need and potential for commercialization;
- Apolitical nature of review and award;
- · Access and assistance by federal program managers;
- Feedback from reviewers for all applicants;
- Diversity of proposal requests to address national needs;
- Funding levels appropriate to the phase of R&D activity.

I urge your continued support of this important program as we all work to increase the competitiveness of U.S.-based companies and raise the U.S. standard of living.

Please do not hesitate to contact me with any questions you have.

Warm regards,

Janet Yancey-Wrona, Ph.D. Governor's Science Advisor Director, Office of Innovation

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